Advanced Management in Providing Pre-exposure Prophylaxis for HIV

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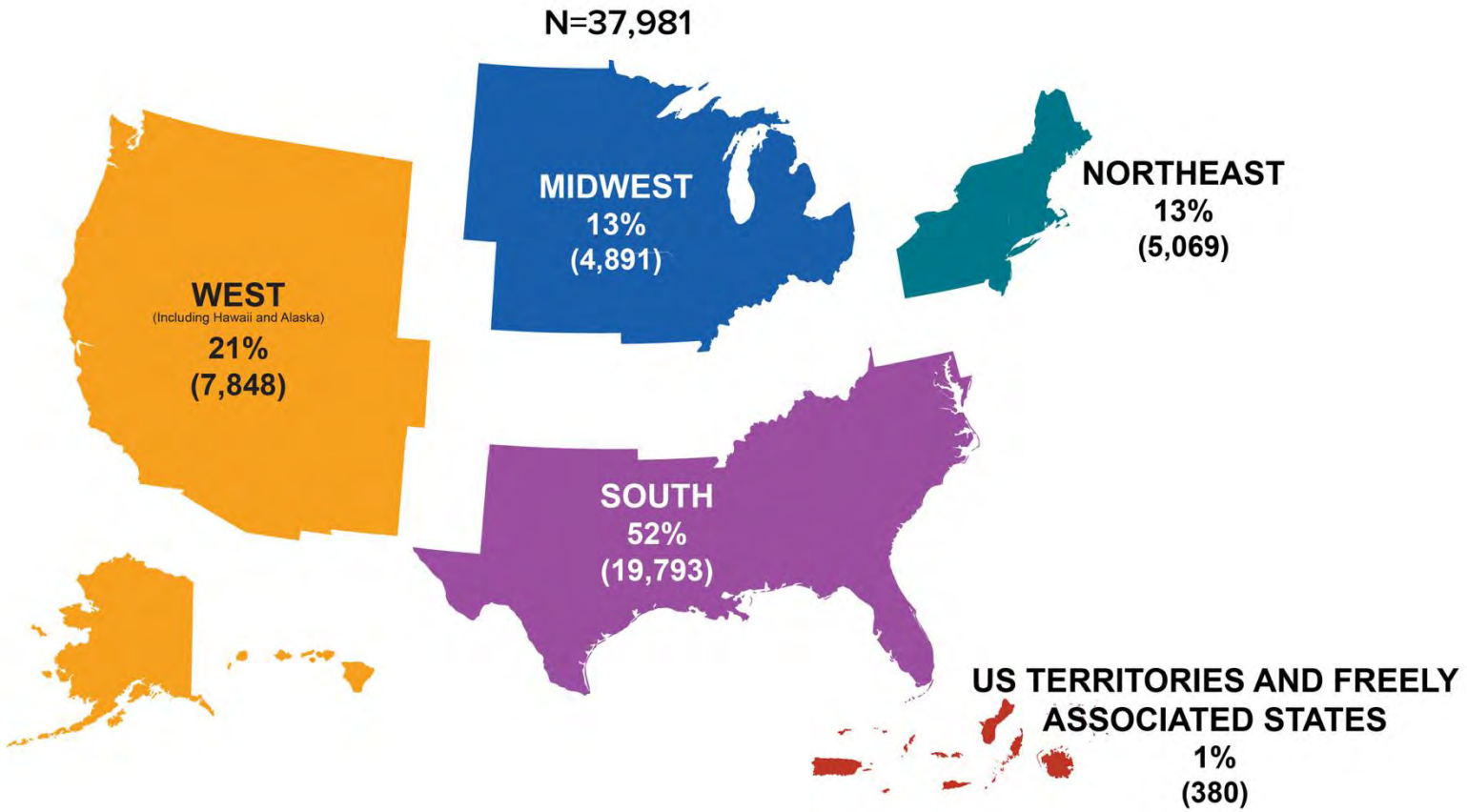
No disclosures to report

Agenda

- Agenda
  - HIV Epidemiology
  - HIV Prevention Update
  - Screening Patients for PrEP
  - Initiating PrEP
  - PrEP On-Demand and Injectable PrEP
  - Questions? Follow Up?

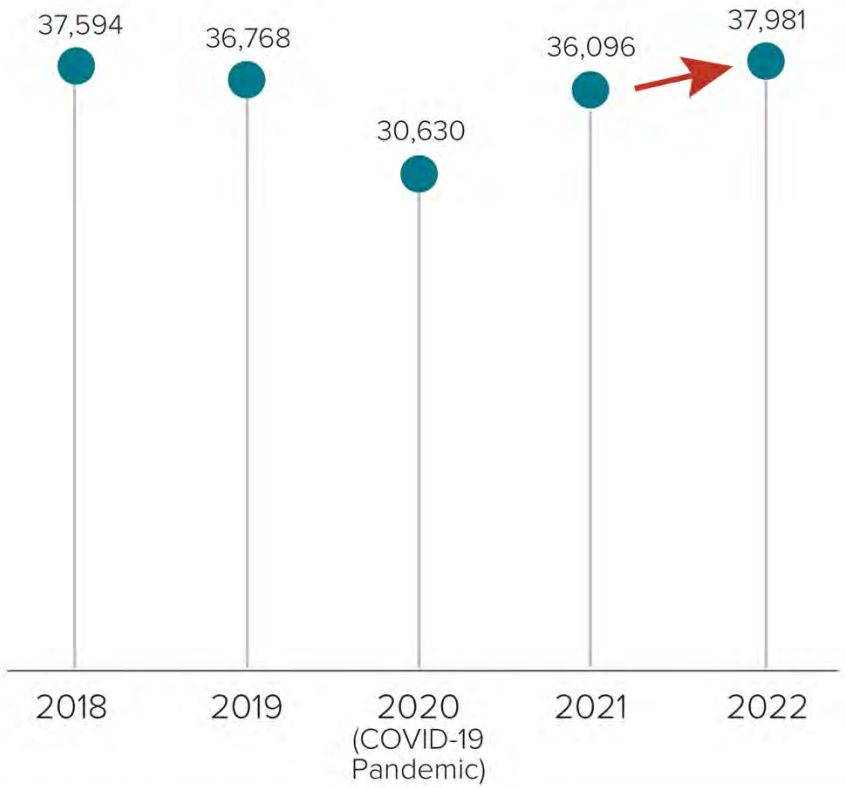
HIV Epidemiology

The South accounted for more than half (52%) of HIV diagnoses in 2022.



Centers for Disease Control and Prevention. Diagnoses, Deaths, and Prevalence of HIV in the United States and 6 Territories and Freely Associated States, 2022. *HIV Surveillance Report* 2024; 35

HIV Epidemiology



5% increase
may be due to post-pandemic effects on the US public health system.

Ending the HIV Epidemic

Overall Goal: Decrease the number of new HIV diagnoses to 9,588 by 2025 and 3,000 by 2030.

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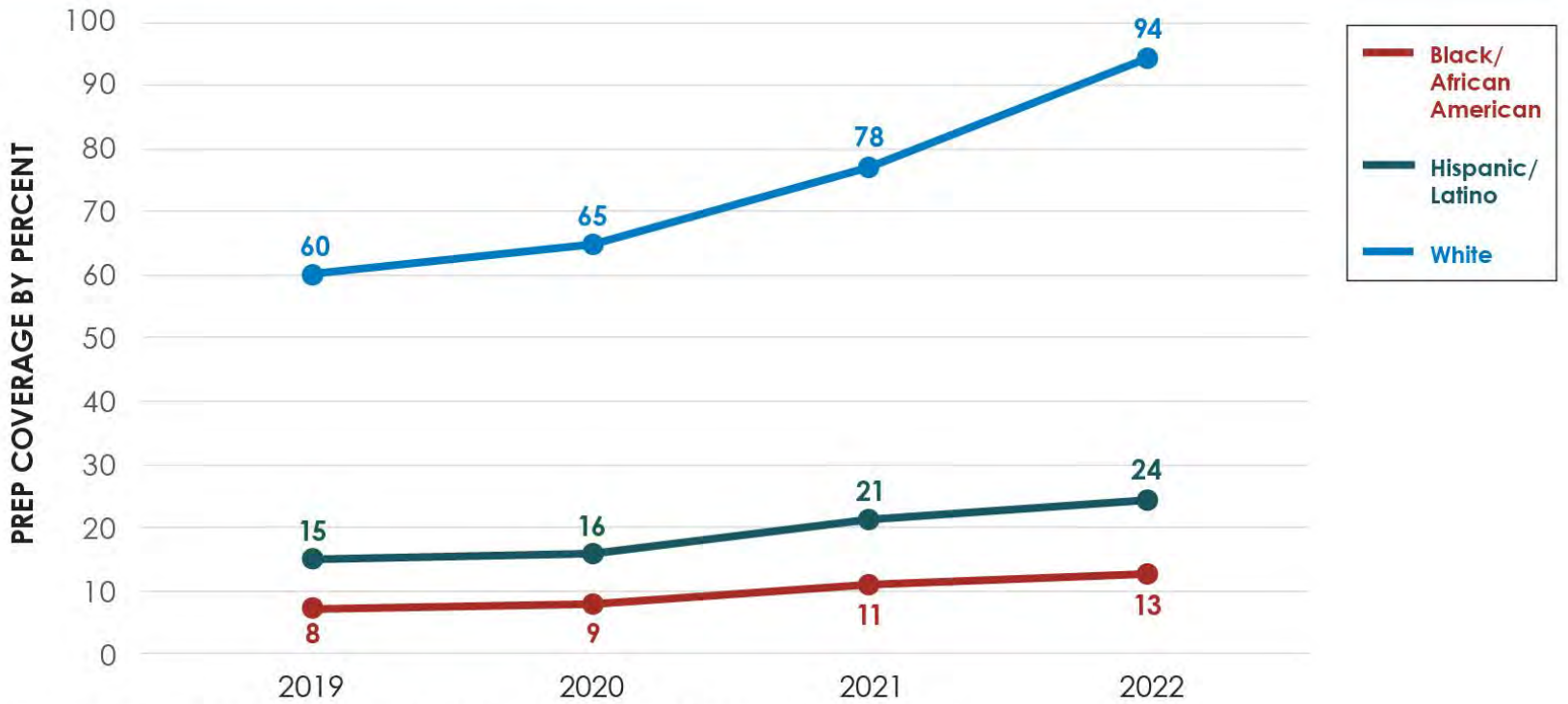
Centers for Disease Control and Prevention. Diagnoses, Deaths, and Prevalence of HIV in the United States and 6 Territories and Freely Associated States, 2022. *HIV Surveillance Report* 2024; 35

TRENDS IN PREP PRESCRIPTIONS AMONG PEOPLE WHO COULD BENEFIT, BY RACE/ETHNICITY, 2019-2022*



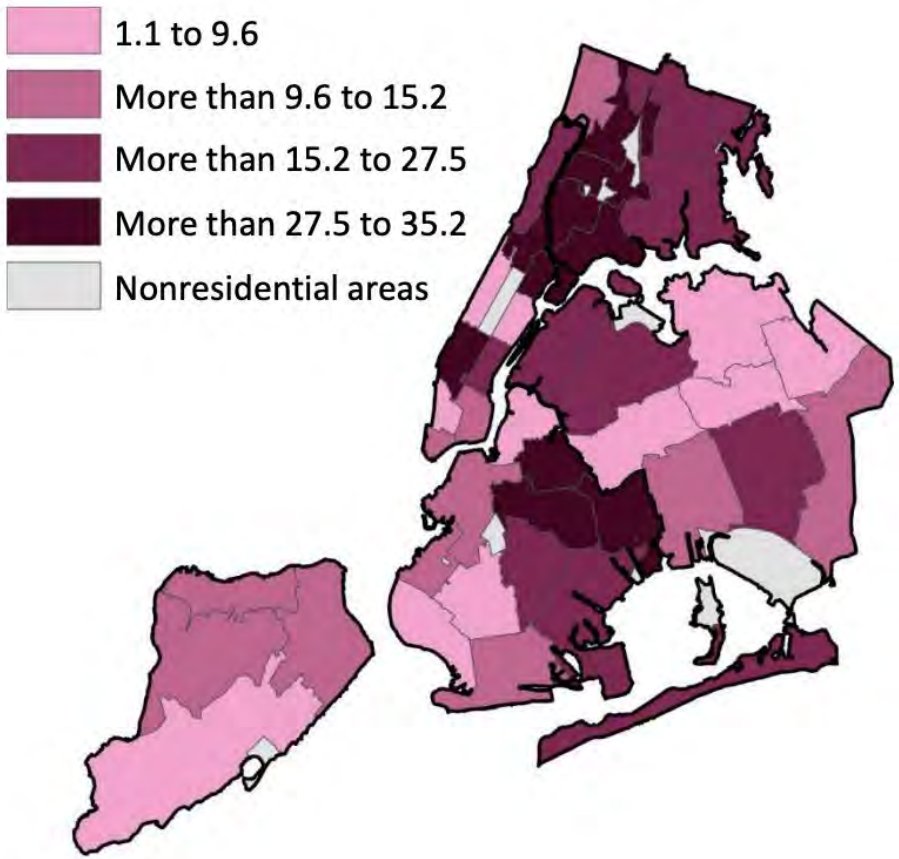
*Data are preliminary. The data on PrEP prescriptions by race and ethnicity are limited, and findings are estimated.

Source: Centers for Disease Control and Prevention

Centers for Disease Control and Prevention. Diagnoses, Deaths, and Prevalence of HIV in the United States and 6 Territories and Freely Associated States, 2022. *HIV Surveillance Report* 2024; 35

New Diagnoses In New York City

Rates of New HIV Diagnoses[3] per 100,000 People in NYC by United Hospital Fund Neighborhood[2] in 2023



New HIV Diagnoses (NYC)

Reduce the number of new HIV diagnoses by **55% to 1,515**

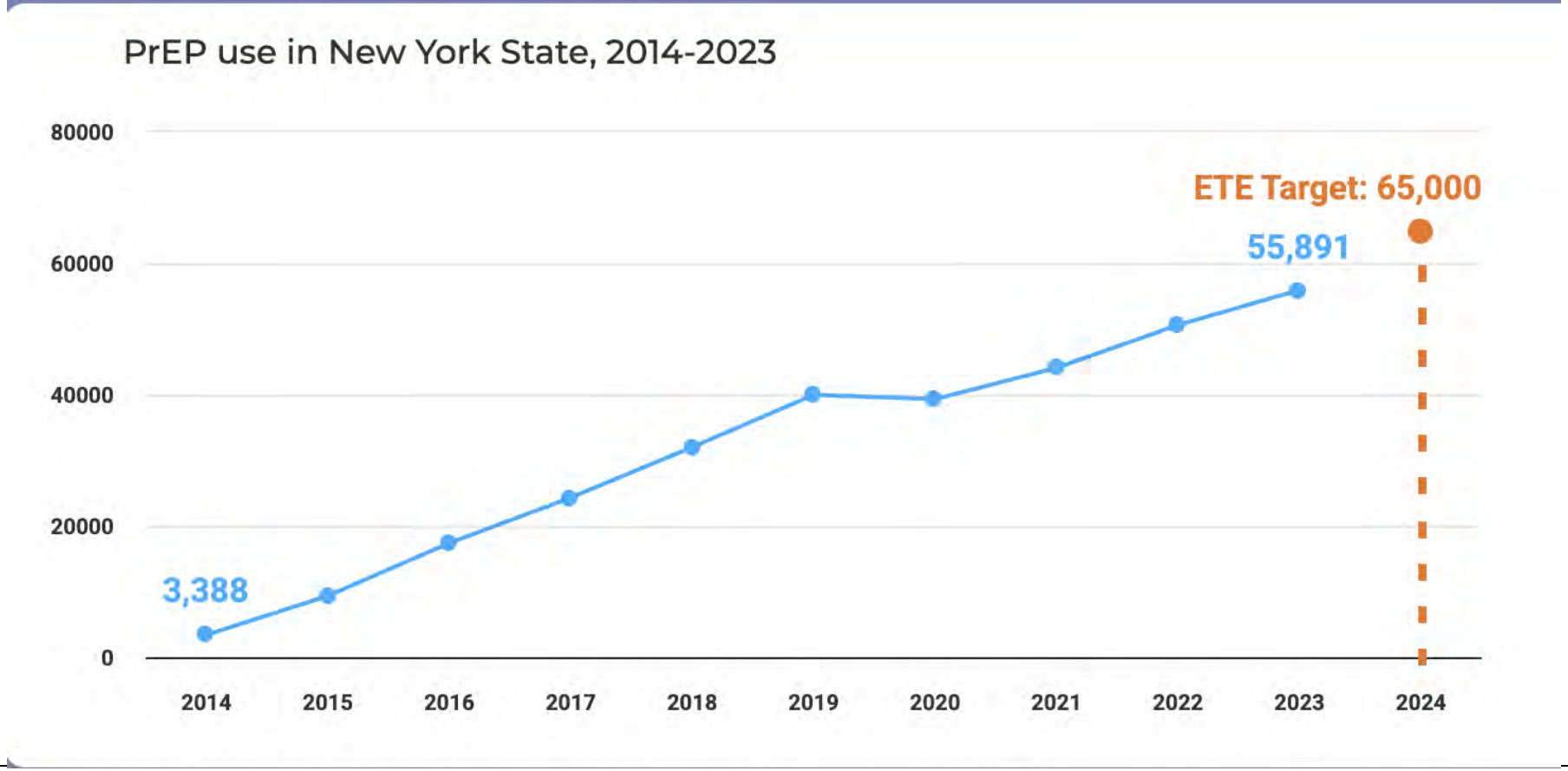
2023 Actual 1,686 (NYC) | Goal 1,350

Chart notes:

- Source: NYC DOHMH HIV Surveillance System
- Number of persons newly diagnosed with HIV.

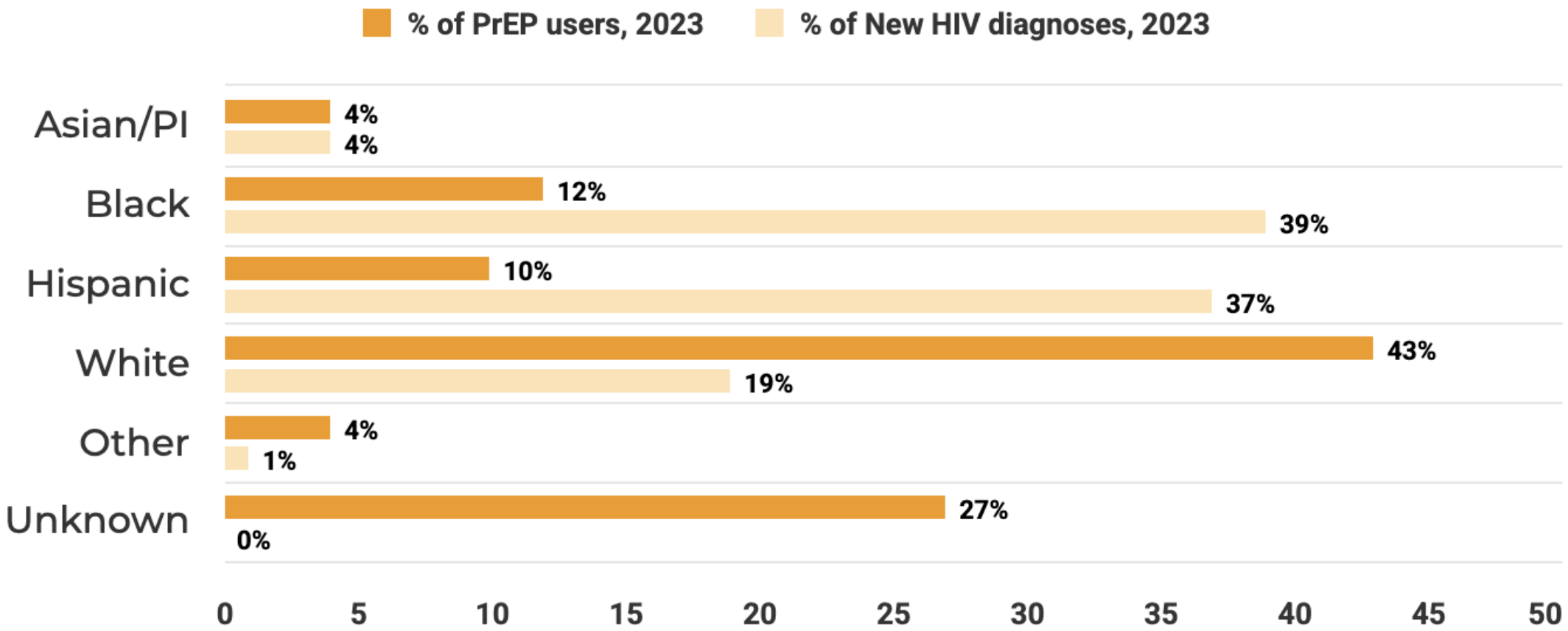
PrEP Uptake In New York

Annual PrEP use has increased overall since 2014, but persistent disparities remain



- IDV® (Integrated Dataverse) from Symphony Health and the NYS Medicaid Data Warehouse (MDW)
- https://etedashboardny.org/data/prevention/prep-nys/

PrEP Uptake in New York City



- IDV® (Integrated Dataverse) from Symphony Health and the NYS Medicaid Data Warehouse (MDW)
- https://etedashboardny.org/data/prevention/prep-nys/

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HIV Prevention Update

Why PrEP?

- Meet Sam!
- A 19-year-old African American male presented to our clinic three times in 2014
- Excellent Student and involved parents
- Reports multiple male sex partners he met online weekly
- During each of the 3 visits in 2014, Sam had rectal gonorrhea
- Our team met this patient a year after he had first seen a provider at our clinic and, sadly, gave a positive test for HIV.
- Pre-Exposure Prophylaxis could have put a stop to this….

Why PrEP?

- Jane is a 27 year old female who started her care with NYP on 1/31/2024 to confirm pregnancy. G5P2112. EDD 10/10/2024
  - First 2 term pregnancy were NSVD
  - Reported 1 male sexual partner at first visit
  - 3/1/2024 at Initial OB Appt: HIV tested negative, partner at visit
  - 7/30/2024 at 3rd Trimester Appt: HIV tested negative, partner at visit
  - 9/19/2024 Scheduled induction and Normal Vaginal Delivery, Newborn Screen sent to state indicated Baby had antibodies for HIV
  - 9/29/2024 - Patient went to a City MD in Jersey and was found to be HIV positive along with the partner
  - What could have been done differently?

What is HIV Pre-Exposure Prophylaxis or HIV PrEP?

Oral PrEP Options

Truvada (TDF/FTC)

- Brand and Generic
- Available and Recommended for anyone
- Daily or On-Demand
  (Approved for MSM only)

Descovy (TAF/FTC)

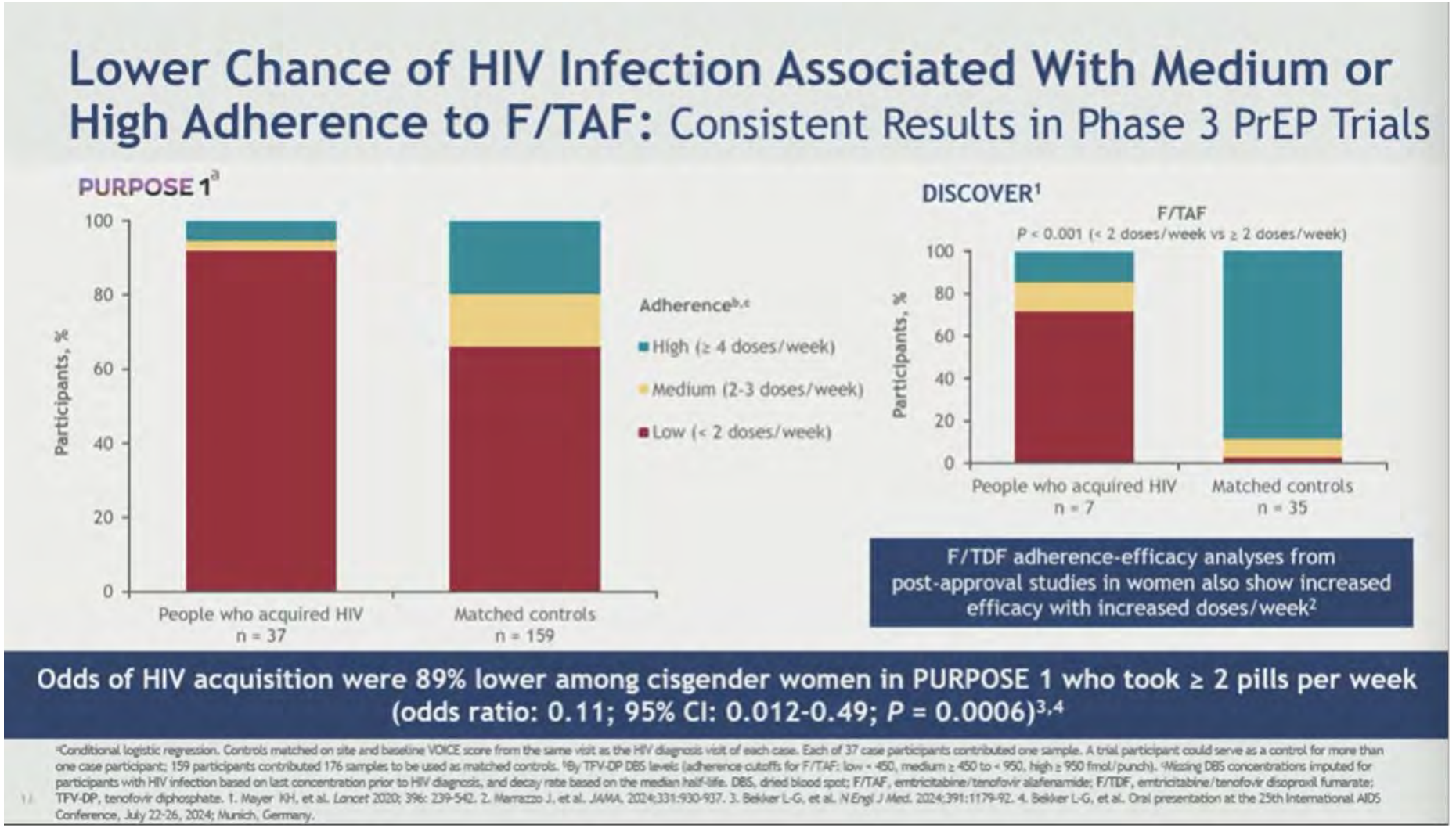
- Only Brand
- *"Approved" only for those MSM and TG, new study indicates effectiveness in women*
- Only Daily
- Smaller pill

- ❖ Both approved for adolescents and adults
- ❖ Both are effective after 7 days in protecting against HIV for anal sex (Truvada – 21 days for vaginal sex)
- ❖ Both need a patient to follow up quarterly for testing with a provider

Oral PrEP Options

TDF/FTC and TDF/TAF are **99% effective** in preventing HIV transmission if taken correctly!

Oral PrEP Options



- Kiweewa FM et al. *Adherence to F/TAF in cisgender women prevents HIV with low risk of resistance or diagnostic delay.* Conference on Retroviruses and Opportunistic Infections, San Francisco, abstract 194, 2025.

Screening For Pre-Exposure Prophylaxis

Screening for HIV Prevention Services

- Screening for PrEP Initiation
  - Prevention Navigators, Disease Intervention Specialists, Coordinators, Nurses, Medical Assistants, Social Workers, and Medical Providers can **all participate in screening for HIV Prevention Services**

Screening for HIV Prevention Services

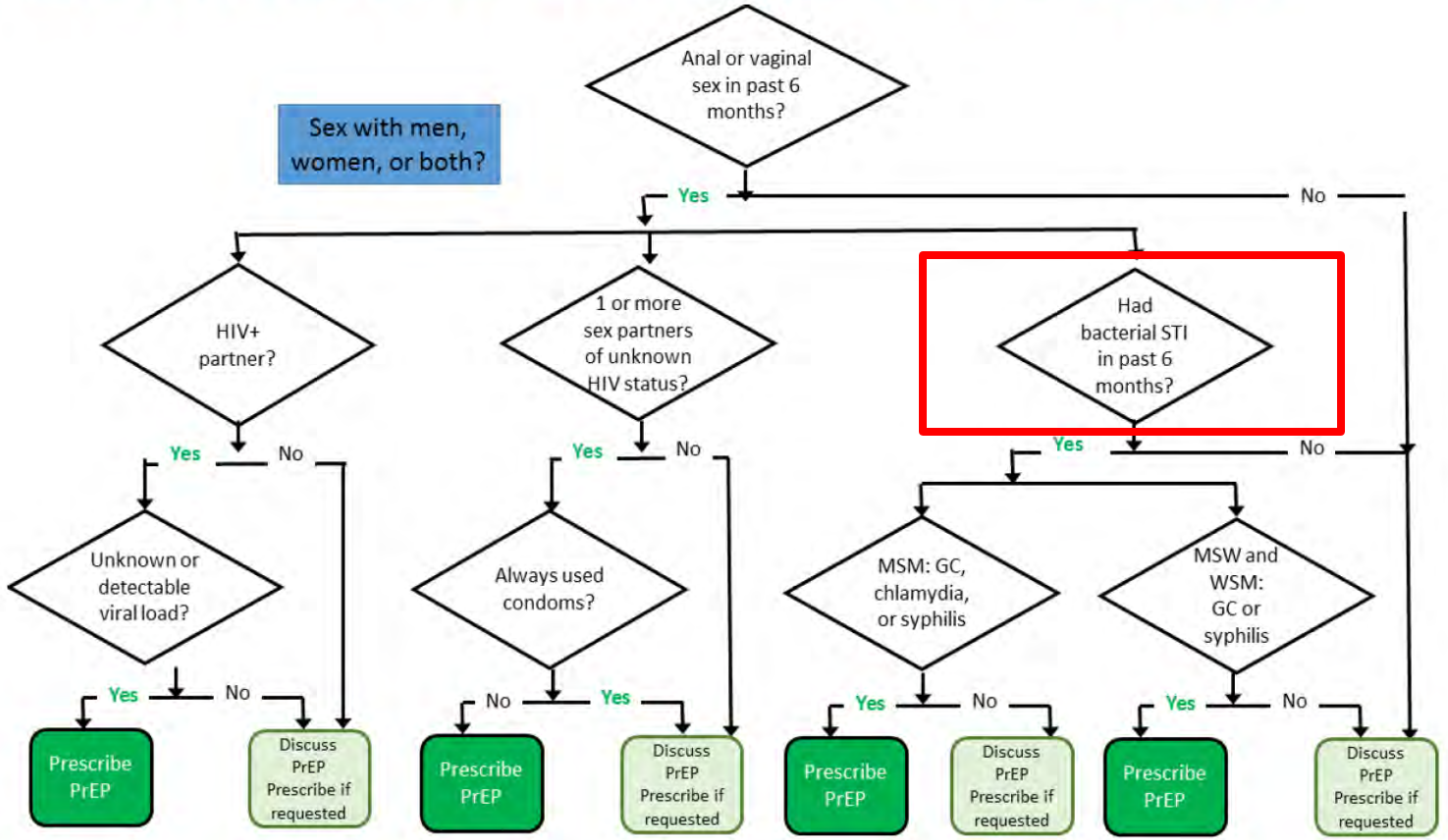
- Who should receive information about PrEP during their medical or outreach visits?
  - The new Updated CDC PrEP 2021 Guidelines state that:

NEW RECOMMENDATION: All sexually active adult and adolescent patients should receive information about PrEP

Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf. Published December 2021

Screening for HIV Prevention Services

PrEP Indications for Sexually Active Persons

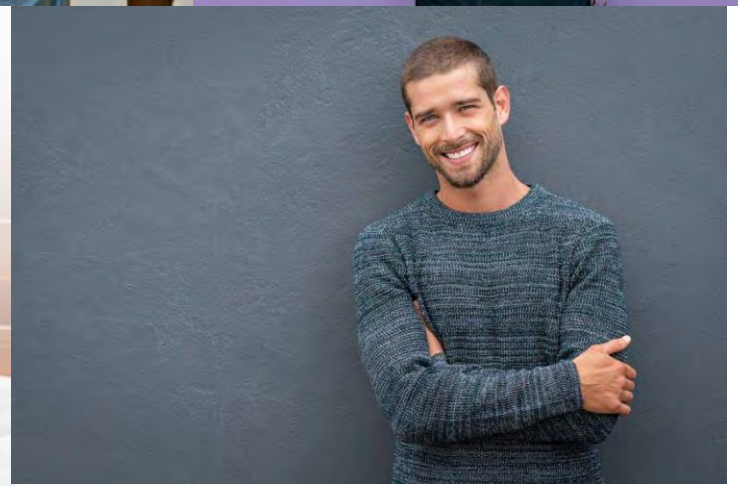


- Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf. Published December 2021.

So…. I should talk to EVERYONE about PrEP?







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So…. I should talk to EVERYONE about PrEP?

NEW RECOMMENDATION: All sexually active adult and adolescent patients should receive information about PrEP

So…. I should talk to EVERYONE about PrEP?

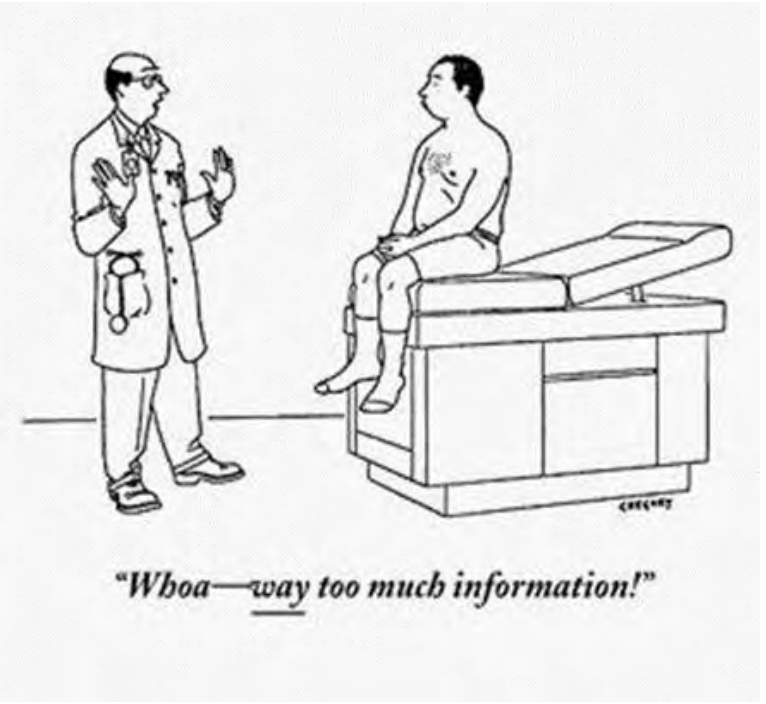
NEW RECOMMENDATION: All sexually active adult and adolescent patients should receive information about PrEP

But how can I tell if they are "at-risk" for HIV? Shouldn't I only talk to patients who are at risk about PrEP?

Discuss/Educate all sexually active clients about PrEP

Screening for HIV Prevention Services

- Sexual History Taking Tips
  - Check in on your own biases
  - Open- Ended Questions
    - "Tell me about your sex life…"
    - "How can I help you to have your ideal sex life…."
  - Use your own voice
  - Avoid the why?
  - What is the *clinical* purpose behind the question you are asking?



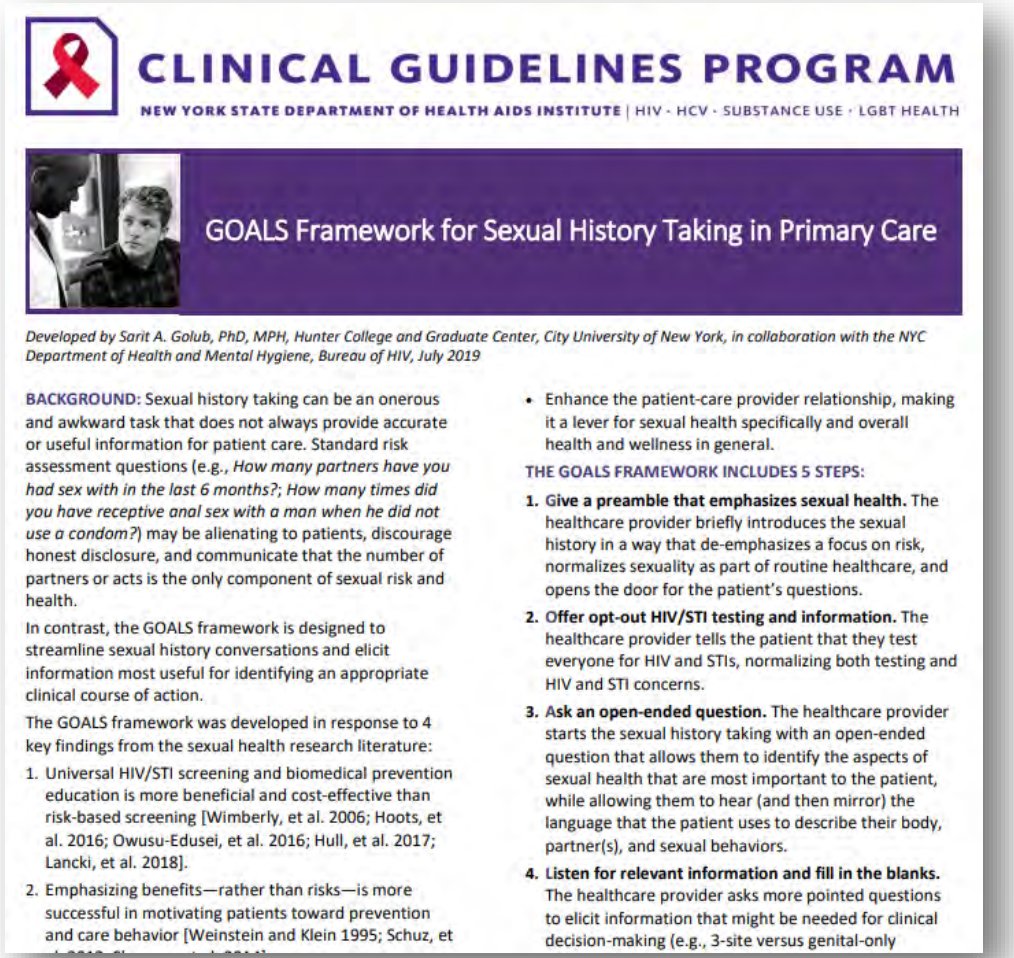
The CDC's 5 Ps – "Partners"

PARTNERS

- In the last 6 months, **have you had a sexual partner** who:
  - Refused to use condoms?
  - Made you have sex when you did not want to?
  - Had sex with anyone beside you?
  - Has ever been to jail or prison?
  - Injected drugs with a needle
  - Has HIV?
  - Is a man who has sex with other men?

- Collier, K. L., Colarossi, L. G., & Sanders, K. (2018). A PrEP Information and Self-Screening Tool for Women. *AIDS Education and Prevention*, *30*(1), 13-25.

Strategy – GOALS Framework



CLINICAL GUIDELINES PROGRAM

NEW YORK STATE DEPARTMENT OF HEALTH AIDS INSTITUTE | HIV · HCV · SUBSTANCE USE · LGBT HEALTH

GOALS Framework for Sexual History Taking in Primary Care

Developed by Sarit A. Golub, PhD, MPH, Hunter College and Graduate Center, City University of New York, in collaboration with the NYC Department of Health and Mental Hygiene, Bureau of HIV, July 2019

BACKGROUND: Sexual history taking can be an onerous and awkward task that does not always provide accurate or useful information for patient care. Standard risk assessment questions (e.g., *How many partners have you had sex with in the last 6 months?; How many times did you have receptive anal sex with a man when he did not use a condom?*) may be alienating to patients, discourage honest disclosure, and communicate that the number of partners or acts is the only component of sexual risk and health.

In contrast, the GOALS framework is designed to streamline sexual history conversations and elicit information most useful for identifying an appropriate clinical course of action.

The GOALS framework was developed in response to 4 key findings from the sexual health research literature:

1. Universal HIV/STI screening and biomedical prevention education is more beneficial and cost-effective than risk-based screening [Wimberly, et al. 2006; Hoots, et al. 2016; Owusu-Edusei, et al. 2016; Hull, et al. 2017; Lancki, et al. 2018].
2. Emphasizing benefits—rather than risks—is more successful in motivating patients toward prevention and care behavior [Weinstein and Klein 1995; Schuz, et

- Enhance the patient-care provider relationship, making it a lever for sexual health specifically and overall health and wellness in general.

THE GOALS FRAMEWORK INCLUDES 5 STEPS:

1. **Give a preamble that emphasizes sexual health.** The healthcare provider briefly introduces the sexual history in a way that de-emphasizes a focus on risk, normalizes sexuality as part of routine healthcare, and opens the door for the patient's questions.
2. **Offer opt-out HIV/STI testing and information.** The healthcare provider tells the patient that they test everyone for HIV and STIs, normalizing both testing and HIV and STI concerns.
3. **Ask an open-ended question.** The healthcare provider starts the sexual history taking with an open-ended question that allows them to identify the aspects of sexual health that are most important to the patient, while allowing them to hear (and then mirror) the language that the patient uses to describe their body, partner(s), and sexual behaviors.
4. **Listen for relevant information and fill in the blanks.** The healthcare provider asks more pointed questions to elicit information that might be needed for clinical decision-making (e.g., 3-site versus genital-only

1. Universal screening is more beneficial and cost-effective than risk-based screening
2. Emphasizing **benefits, rather than risks**, is more successful in motivating patients
3. **Positive interactions** with healthcare providers **promote engagement** in prevention and care
4. Patients want their healthcare providers to talk with them about sexual health

- https://www.hivguidelines.org/hiv-care/selected-resources/goals-framework/

Initiating Pre-Exposure Prophylaxis

Screening for HIV Prevention Services

- Initial Clinical Assessment
  - When was the ***last time the patient had sex without a condom*** (while not on PrEP)?
  - When was the patient's ***last HIV test?***
  - Past medical history (any history renal disease or Hepatitis B)

Screening for HIV Prevention Services

- Initial Clinical Assessment
  - When was the ***last time the patient had sex without a condom*** (while not on PrEP)?

Within the last 72 hours

YES → Consider Post Exposure Prophylaxis or "PEP" and then transition to PrEP after 28 days

NO → Try for Same-day PrEP start

Post Exposure Prophylaxis

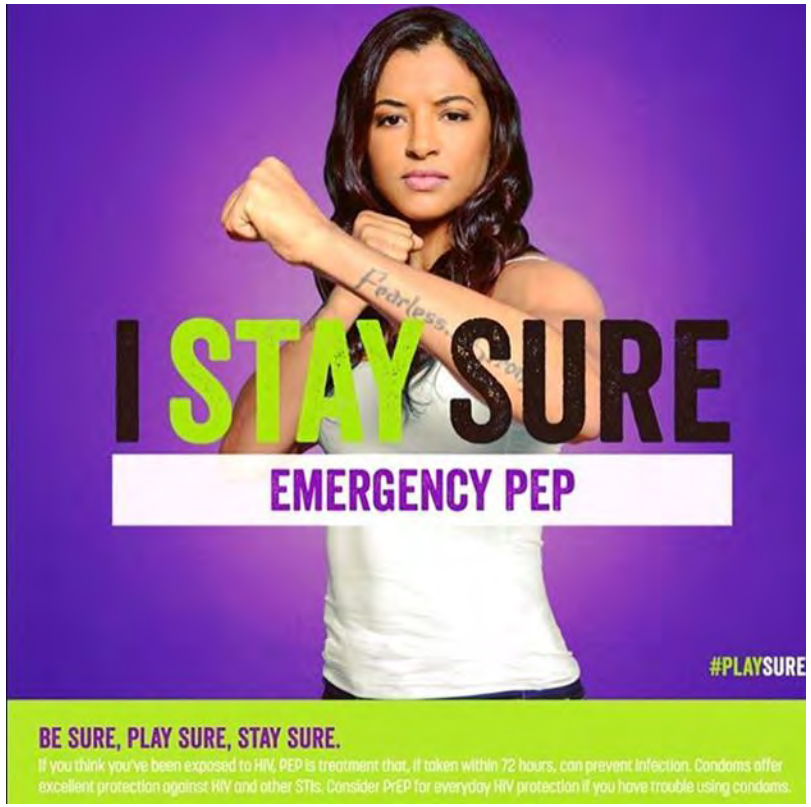
- **Post Exposure Prophylaxis "PEP"**
  - A three-four drug combination therapy given to a patient for 28 days after an HIV exposure, i.e.:
    - Needlestick
    - Sexual encounter (consensual or non-consensual)
    - Significant contact with Blood products that penetrates skin or mucous membrane
  - **Must start within 72 hours of HIV exposure and complete the entire 28 days for medications to be effective**

Post Exposure Prophylaxis

Bictegravir/emtricitabine/tenofovir alafenamide "Biktarvy"
(once a day)
Taken for 28 days

Tenofovir + **Emtricitabine** 200/300mg (once a day)
AND
Dolutegravir 50mg (once a day)
Taken for 28 days

Tenofovir + **Emtricitabine** 200/300mg (once a day)
AND
Raltegravir 400mg (twice a day)
Taken for 28 days



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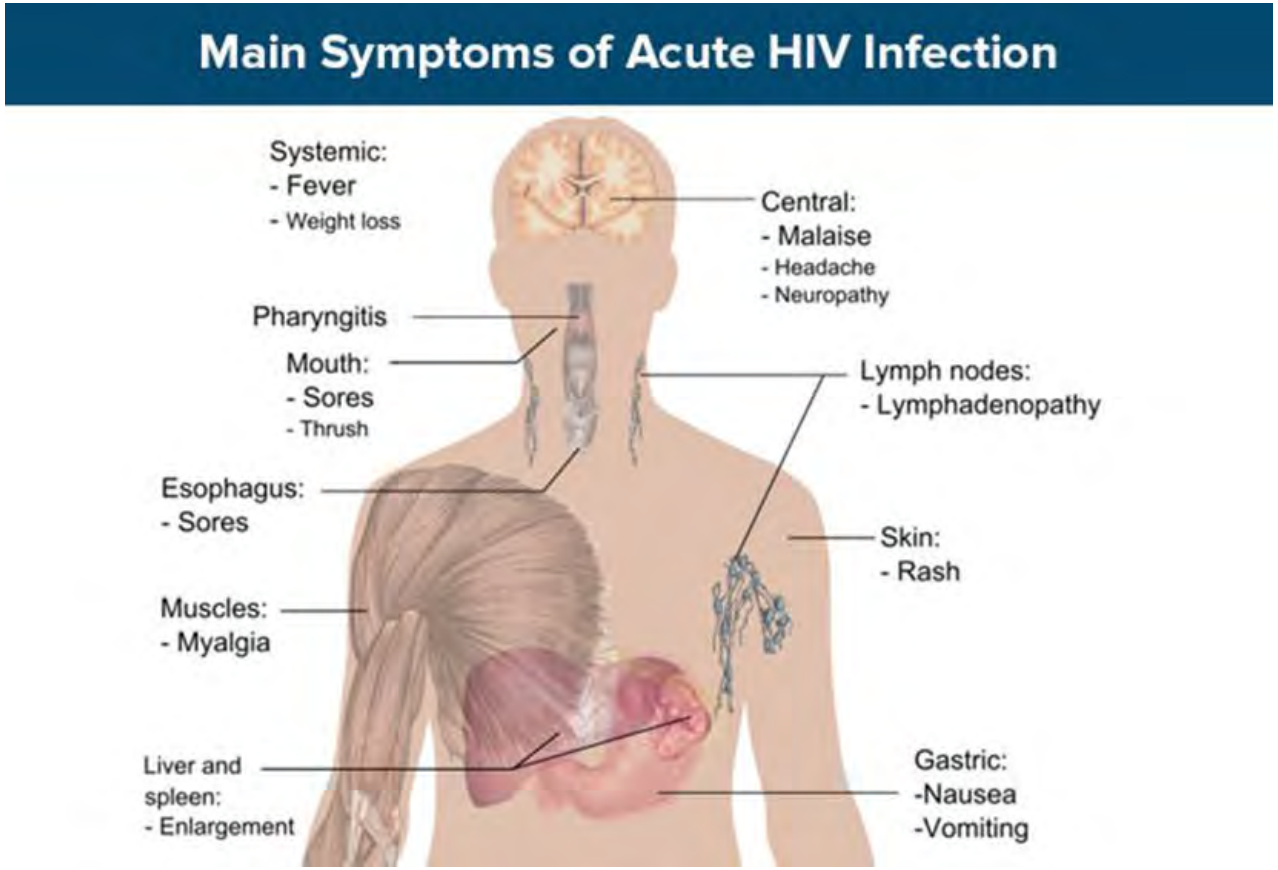
For Alternative Regimens: Dominguez, K. L., Smith, D. K., Thomas, V., Crepaz, N., Lang, K., Heneine, W., . . . Nesheim, S. R. (2016). Updated guidelines for antiretroviral postexposure prophylaxis after sexual, injection drug use, or other nonoccupational exposure to HIV—United states, 2016. doi:www.cdc.gov/hiv/risk/pep/ (Appendix 4)

Screening for HIV Prevention Services

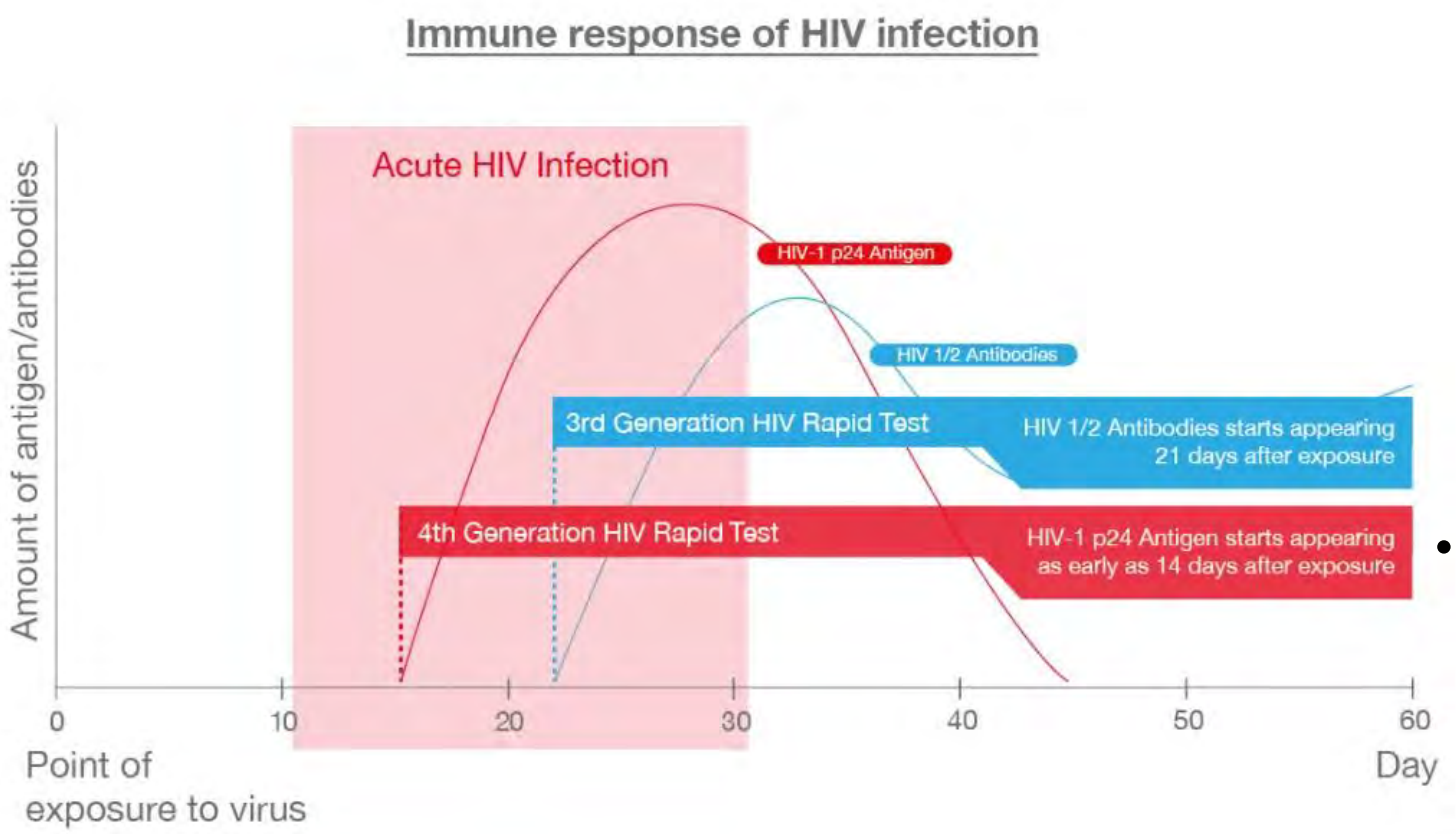
- Initial Clinical Assessment
  - When was the patient's ***last HIV test***?

Screening for HIV Prevention Services



- Within 2 to 4 weeks after infection with HIV, about two-thirds of people will have symptoms of a flu-like illness
- With 4th generation HIV tests being widely available, someone may present with these symptoms and test positive for HIV

HIV Test Counseling



- **Fourth-generation testing** incorporates HIV-1/HIV-2 antibody and p24 antigen detection; therefore, the window period can be as **early as 14 to 17 days** since exposure
  - Patients at risk should be retested 3-4 weeks after exposure for a definitive negative test
- **Third generation testing** incorporates HIV-1/HIV-2 and starts appearing **between 21- 60 days after exposu**re
  - Over the counter tests are 3rd Generation (Orasure/Oraquick)

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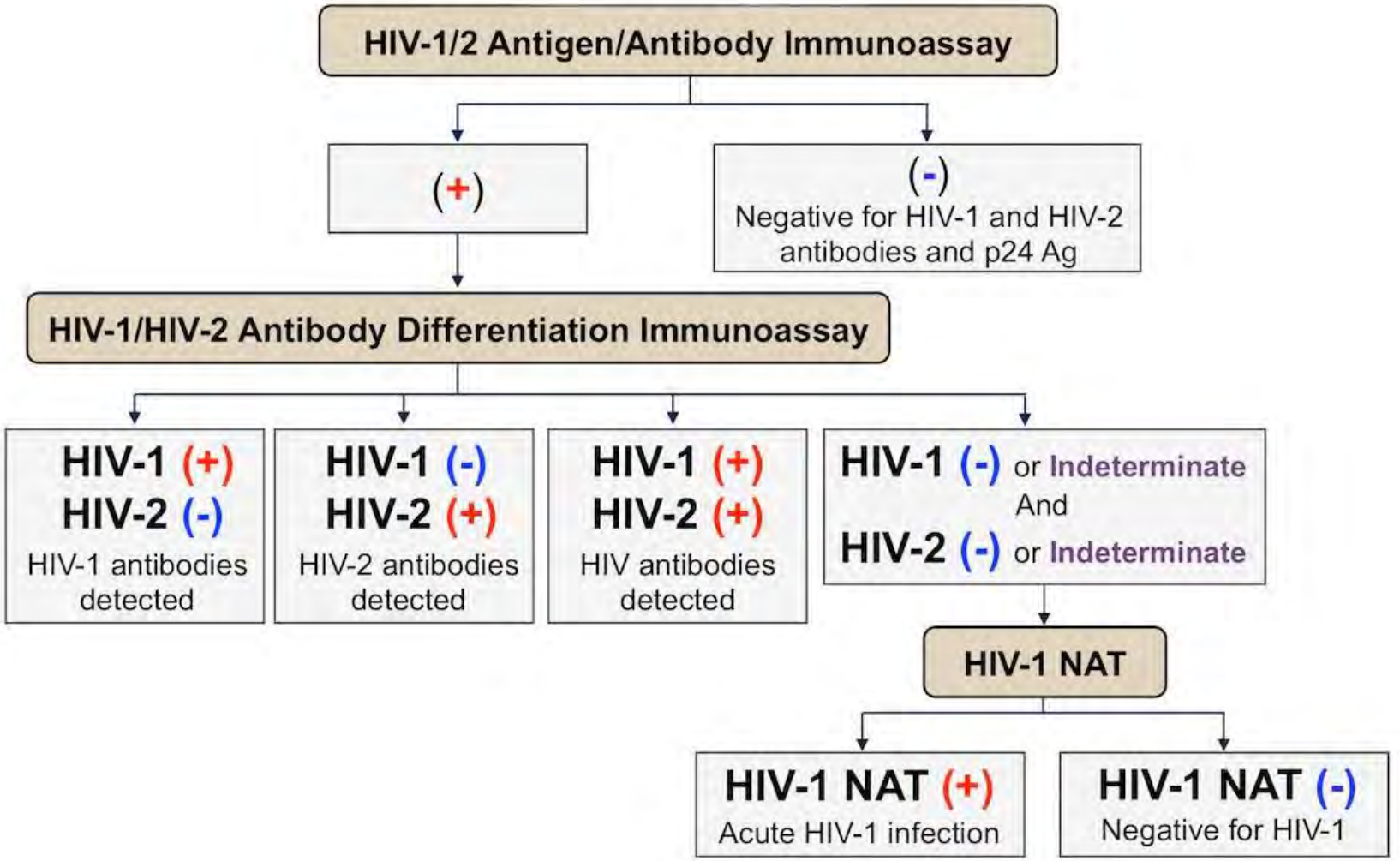
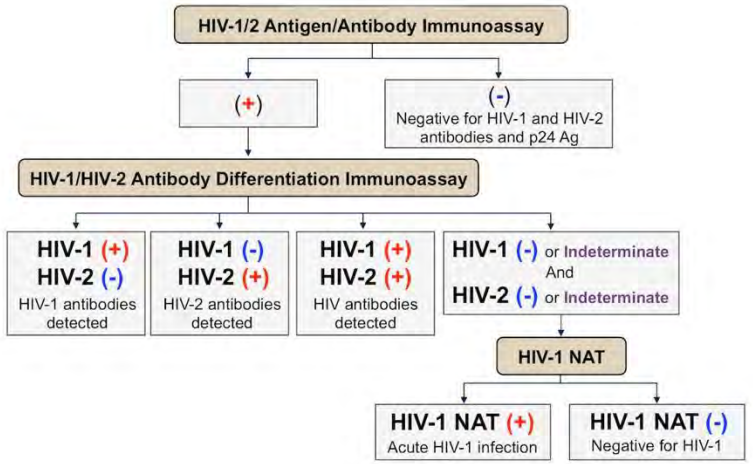
Reprinted from Patel P, Bennett B, Sullivan T, Parker MM, Heffelfinger JD, Sullivan PS; CDC AHI StudyGroup. Rapid HIV screening: missed opportunities for HIV diagnosis and prevention. J Clin Virol. 2012;54(1):43, with permission from Elsevier. http://www.sciencedirect.com/science/journal/13866532.

HIV Testing Algorithm



HIV Testing Algorithm



HIV 1/2 AG/AB COMBINATION SCREEN

Status: **Final result** Connect: **Auto-Release Prevented**

	Value	Range
HIV Ab/Ag Screen	**Reactive (A)**	Nonreactive
HIV Ab/Ag Screen Interp	Presumptive evidence for HIV-1 antigen or HIV-1/HIV-2 antibodies. This result is preliminary. Reflex testing for HIV-1/2 Antibody Supplemental testing has been initiated. Results from this confirmatory testing must be considered in making a diagnosis related to HIV infection.	

Comments:
RRT@PAGED@1/20/2023 12:55:33 AM EST

HIV 1/2 SUPPLEMENTAL AB (REFLEX TEST)

Status: **Final result** Connect: **Auto-Release Prevented**

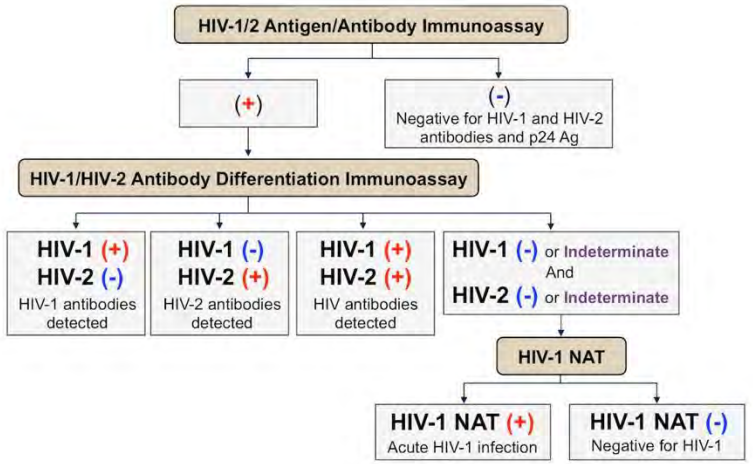
Newer results are available. Click to view them now.

	Value	Range
HIV-1 Antibody	**Nonreactive**	Nonreactive
HIV-2 Antibody	**Nonreactive**	Nonreactive
HIV-1/2 Supplemental Interp	**HIV Ab NEGATIVE**	HIV Ab NEGATIVE

Performing Lab: NYP_Columbia CLIA: 33D0664187
Director: HOD, M.D.,ELDAD A. Address: 622 West 168th Street New York NY 10032

Narrative
Ordered due to positive HIV Ab/Ag result.

HIV Testing Algorithim



HIV-1 VIRAL LOAD, REAL-TIME PCR — Collected 1/19/2023
HIV-1 RNA, PCR `Not Detected`
HIV 1 RNA LOG COPIES `Not Detected`

HIV 1/2 AG/AB COMBINATION SCREEN — Collected 1/19/2023
HIV 1/2 AB & HIV1 P24 AG **`Reactive !`**
HIV AB/AG SCREEN INTERP `Presumptive evidence for HIV-1 antige...`

HIV-1 QUALITATIVE BY NAAT — Collected 1/19/2023
HIV 1 RNA, BLD, QL, NAAT `Not Detected`

HIV 1/2 SUPPLEMENTAL AB (REFLEX TEST) — Collected 1/19/2023
HIV-1 AB, EIA `Nonreactive`
HIV-2 AB `Nonreactive`
HIV-1/2 AB INTERP `HIV Ab NEGATIVE`
Includes: Narrative

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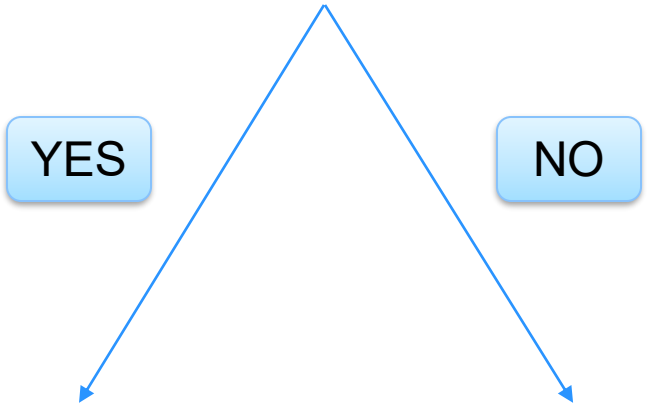
HIV Testing

- Take Away Notes about 4th generation HIV testing
  - Always **ask when their last unprotected/condomless sexual encounter** was (provides you with a window period about the test). If within the last two weeks = consider viral load testing (NAAT/PCR) if you are able to order
  - False positives are a definite possibility (Ab/Ag= Positive; Confirmatory = Negative)
    - 20 out of 10,000 4th Generation HIV tests will be a “false positive” in a high prevalence area
  - **Order the test!** Identify an “expert” at your institution and call them if you need them

- https://www.cdc.gov/hiv/pdf/testing/cdc-hiv-factsheet-false-positive-test-results.pdf

Screening for HIV Prevention Services

- Initial Clinical Assessment
  - Does patient have a history of renal disease?



Ensure that CrCl is ≥60 mL/minute before initiating F/TDF as PrEP, or ≥30 mL/minute before initiating F/TAF as PrEP

Try for Same-day PrEP start

https://www.cdc.gov/hiv/clinicians/prevention/prep.html

Screening for HIV Prevention Services

- Initial Clinical Assessment
  - Does patient have a history of Chronic Hepatitis B?
    - TDF/FTC & TAF/FTC are active against HIV and HBV
    - Those who test positive for hepatitis B surface antigen (HBsAg) should be co-managed by a specialist in infectious or hepatic disease.
    - ***BEFORE*** PrEP is prescribed be sure to test HBV DNA to determine the quantitative level of viral replication

Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2017 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf. Published March 2018.

Essentials to PrEP Clinic Implementation
Medical Visit

- Initial Labs
  - **HIV Test (4th generation if available) – required**
    - **HIV Ab/Ag and HIV viral load test**
  - **Basic Metabolic Panel (Creatinine) – required**
  - Serology for Viral Hepatitis A, B, and C
  - 3 site Gonorrhea/Chlamydia Testing
  - Syphilis Testing
  - Pregnancy Test

- Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf. Published December 2021

Write that Prescription!

- Depending on the patient's insurance:
  - Insured
    - emtricitabine/tenofovir disoproxil 200/300 mg
      - One tab once daily for 30 days Quant 30
      - No refills if first visit, 3 refills if quarterly
  - Using patient assistance program (Gilead)
    - emtricitabine/tenofovir alafenamide "Descovy" 200/25 mg
      - One tab once a day for 30 days Quant 30
      - No refills if first visit, 3 refills if quarterly

Essentials to PrEP Clinic Implementation
Follow up Medical Visit Support

PreExposure Prophylaxis Follow Up Visit Lab Schedule					
	Baseline	(1 month)	every 3 Months	every 6 months	every 12 months
Clinic Visit	X	X	X		
HIV Testing *	X	X	X		
STI Testing (3 site GC/CT and Syphilis testing)	X	X	X		
Pregnancy Test	X	X	X		
Lipid Panel (TAF/FTC or "Descovy" only)	X				X
BMP (Serum Creatinine and estimated eCrCL	X	X		Age >/50 **or** eCrCl <90 ml/min at baseline	Age <50 or eCrCl <90 ml/min at baseline
Hepatitis A & B serology (including: HepA IgG, Hepatitis B surface antigen, Hepatitis B surface antibody)	X	provide appropiate immunization			
Hepatitis C antibody test	X				X

() = outside of CDC recommendations

HIV Test
4th generation HIV ab/ag test
AND
(HIV qualitative/quantitative NAAT if patient is actively taking PrEP or receiving injections)

- Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf. Published December 2021

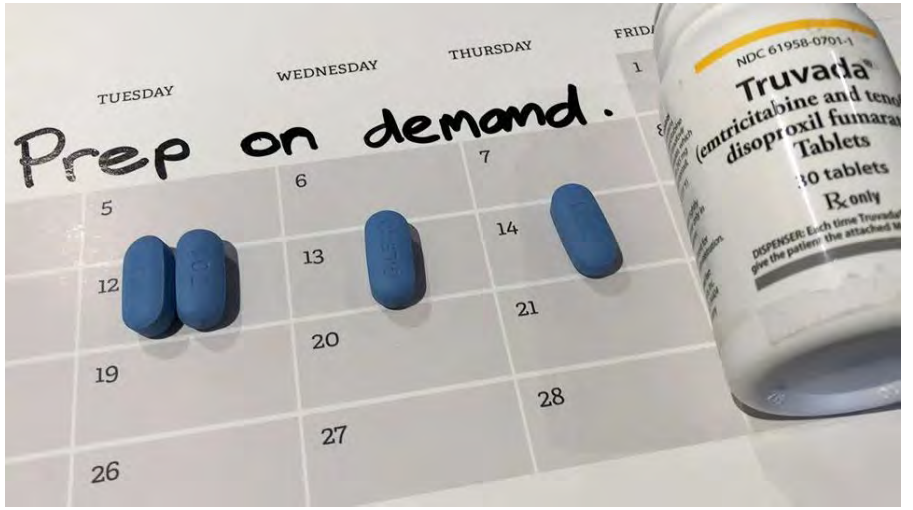
On Demand Dosing

PrEP On-Demand

- Definition
  - *"On-Demand"* or *"Event-Based"* or *"2:1:1"* or *"Intermittent"* or *"Peri-coital" or "Vacation"* PrEP
    - Any dosing schedule variation that is not "Daily Dosing"
  - Taking PrEP, specifically Truvada (TDF/FTC), around the time of a sexual encounter(s) or "riskier" periods
    - Truvada is the only pre-exposure prophylaxis medication recommended for On-Demand at this time

PrEP-On-Demand: Patient Evaluation

- Screening for On-Demand Dosing
  - Men who have sex with Men (MSM)
  - Has sex ***less than*** twice a week
  - Patient able to adhere to quarterly visits/STI screening in the absence of a quarterly prescription trigger
  - Expressed understanding of dosing schedule

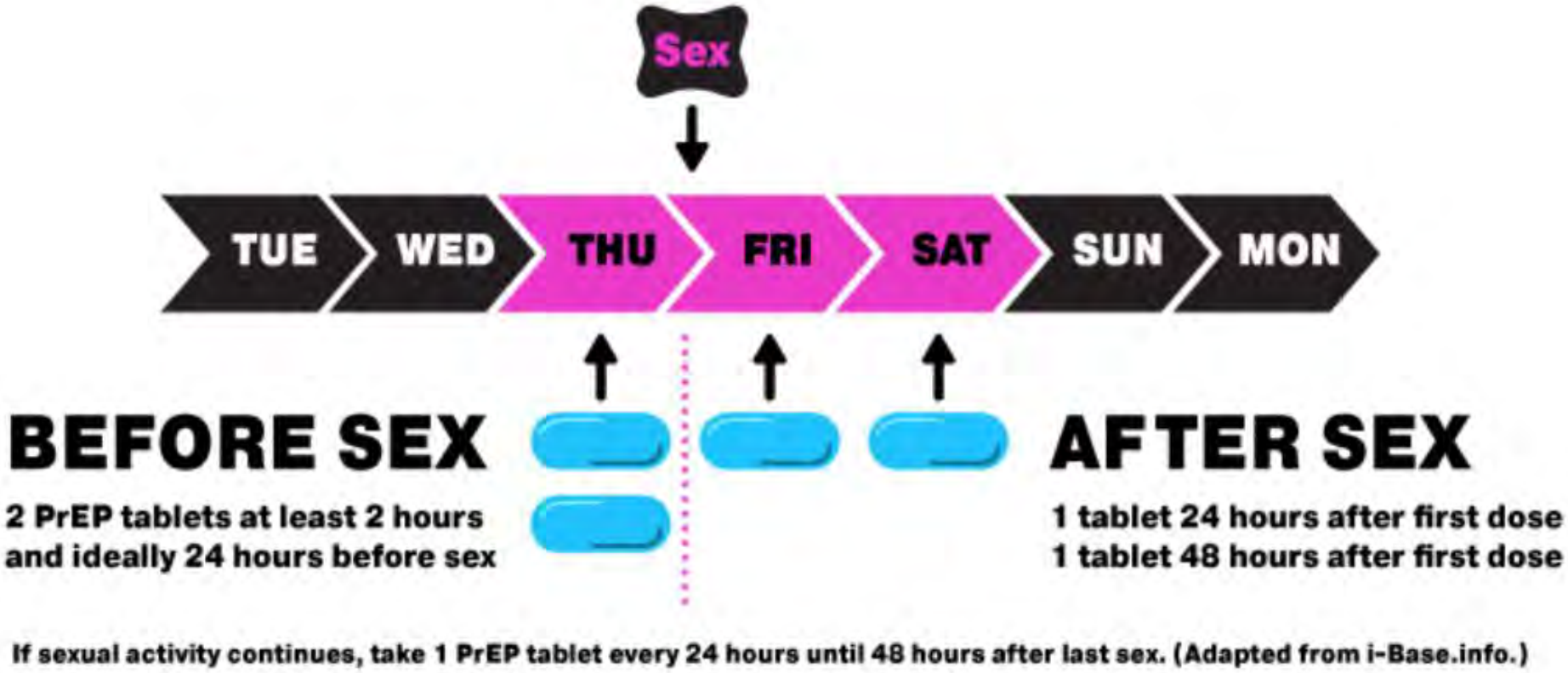


PrEP-On-Demand: Patient Evaluation

- Exclusion Criteria
  - Individuals engaging in vaginal sex
  - IV Drug users
  - Adolescents (due to documented hx of adherence difficulties in ATN studies)
  - Individuals engaging in sex more than twice a week
  - Individuals taking TAF/FTC or *Descovy*

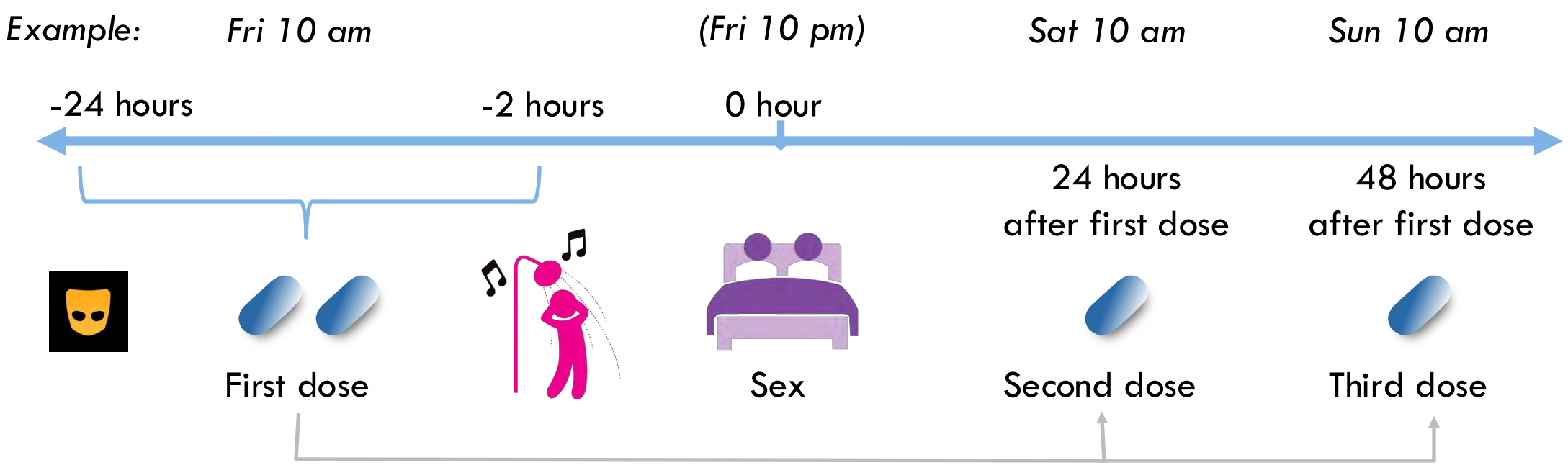
- Cottrell, M. L., Yang, K. H., Prince, H. M., Sykes, C., White, N., Malone, S., ... & Kashuba, A. D. (2016). A translational pharmacology approach to predicting outcomes of preexposure prophylaxis against HIV in men and women using tenofovir disoproxil fumarate with or without emtricitabine. *The Journal of infectious diseases*, *214*(1), 55-64.
- Anderson, P. L., García-Lerma, J. G., & Heneine, W. (2016). Non-daily pre-exposure prophylaxis for HIV prevention. *Current opinion in HIV and AIDS*, *11*(1), 94.

PrEP On Demand: Dosing Schedules



- https://www1.nyc.gov/assets/doh/downloads/pdf/ah/prep-on-demand-dosing-guidance.pdf

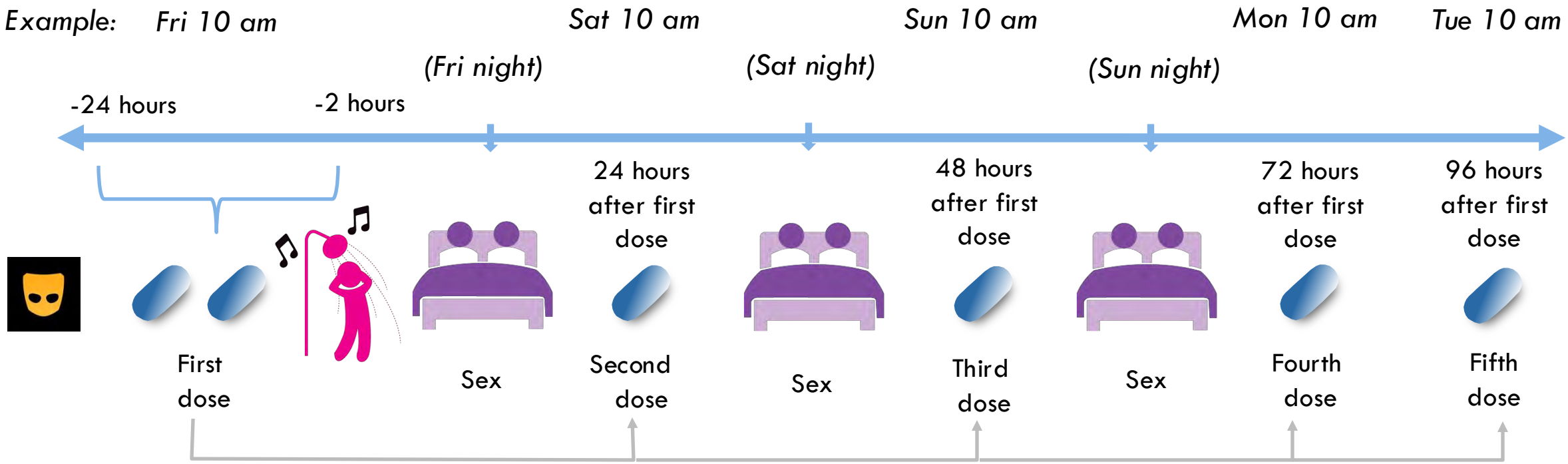
PrEP On Demand: Dosing Schedule



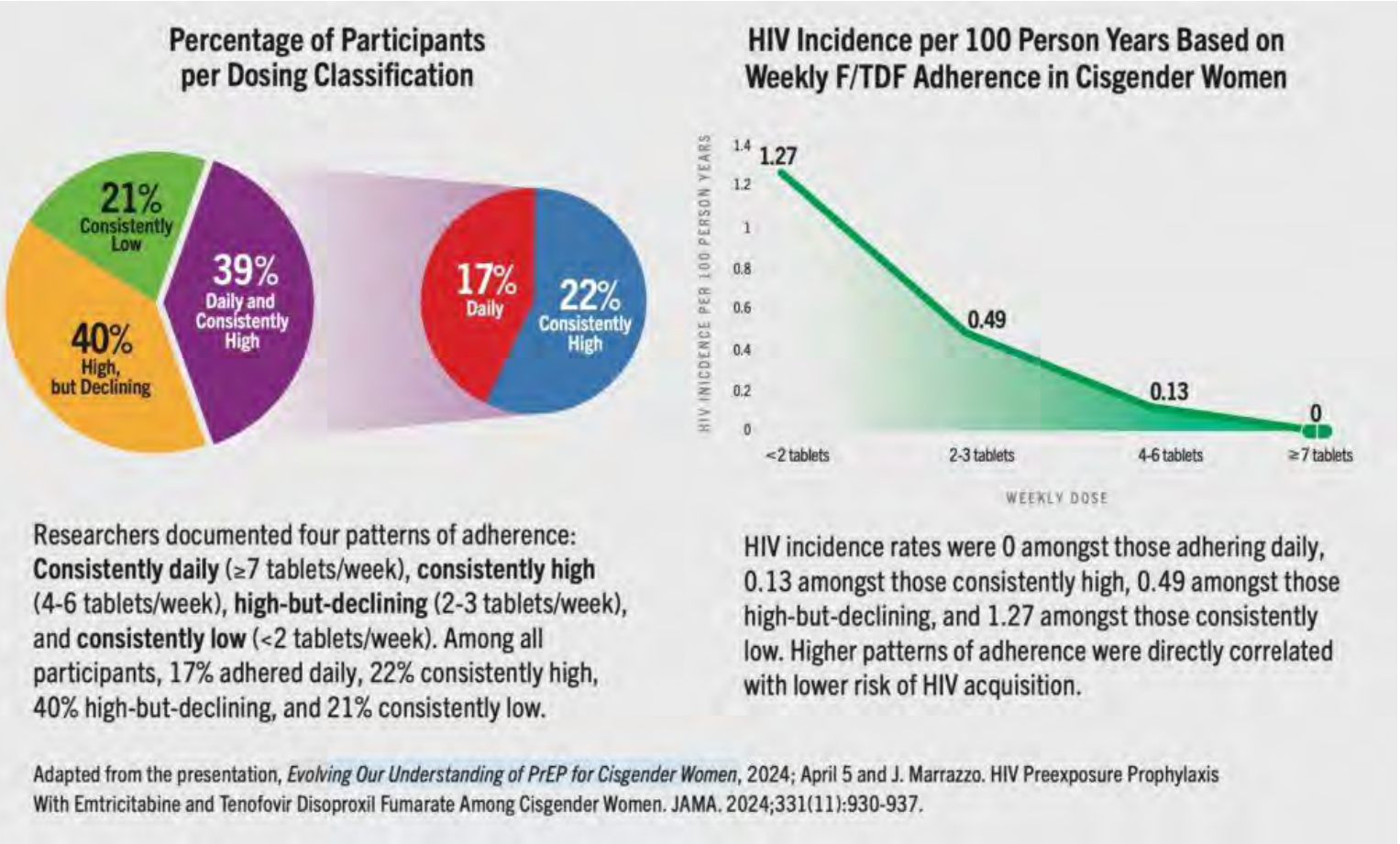
PrEP On-Demand: Dosing Schedule

- Dosing Schedule Variations
  - Sexual experiences usually don't fit into a 2:1:1 format
  - First dose 2-24 hours before sex
  - 48 & 72 hour dose is based on first dose NOT when the individual has sex
  - If the individual keeps having sex make sure to take PrEP every 24 hours until 2 days after last sex

PrEP On Demand: Dosing Schedule



PrEP On-Demand For Women?



Researchers documented four patterns of adherence: **Consistently daily** (≥7 tablets/week), **consistently high** (4-6 tablets/week), **high-but-declining** (2-3 tablets/week), and **consistently low** (<2 tablets/week). Among all participants, 17% adhered daily, 22% consistently high, 40% high-but-declining, and 21% consistently low.

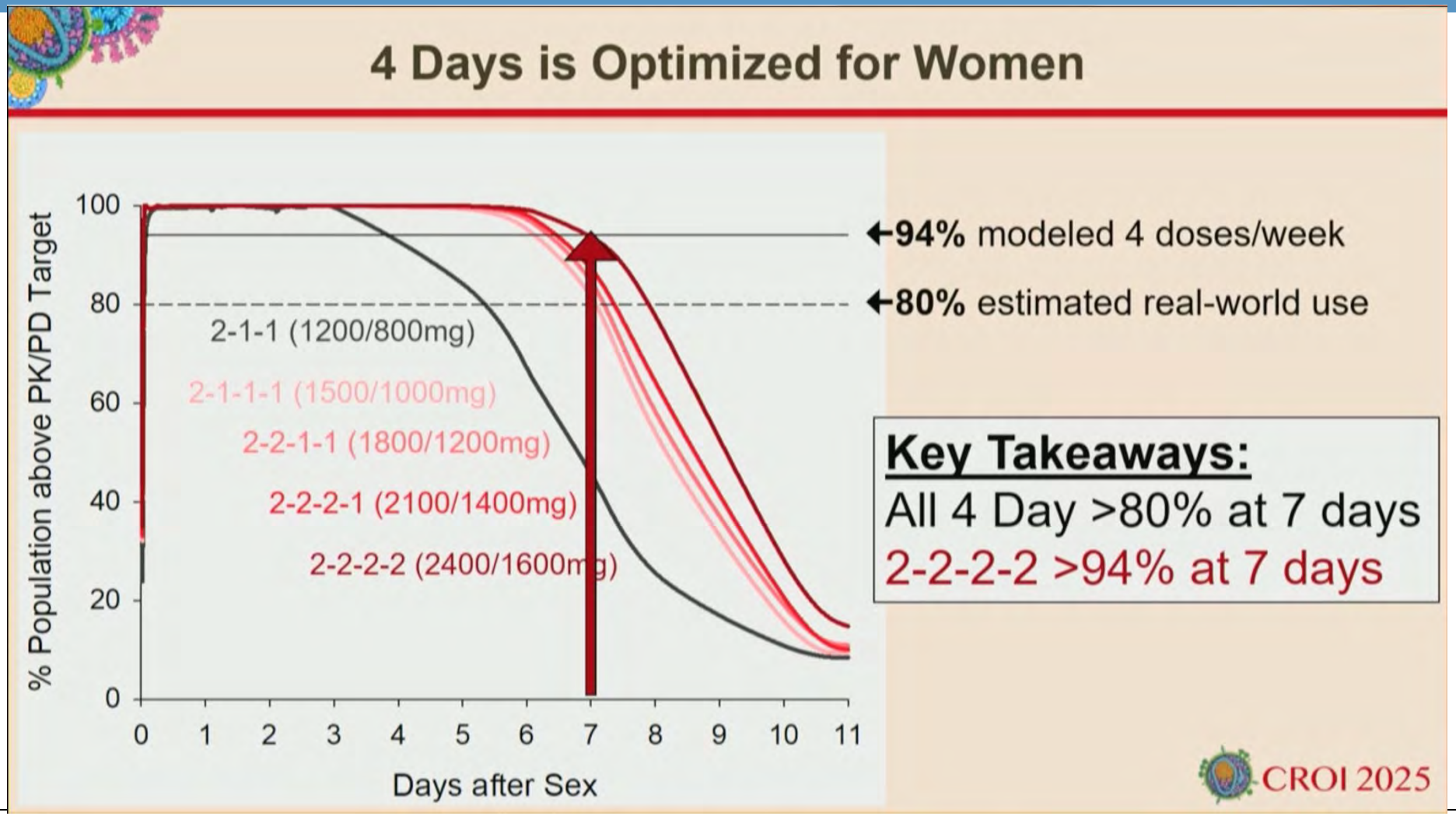
HIV incidence rates were 0 amongst those adhering daily, 0.13 amongst those consistently high, 0.49 amongst those high-but-declining, and 1.27 amongst those consistently low. Higher patterns of adherence were directly correlated with lower risk of HIV acquisition.

Adapted from the presentation, *Evolving Our Understanding of PrEP for Cisgender Women*, 2024; April 5 and J. Marrazzo. HIV Preexposure Prophylaxis With Emtricitabine and Tenofovir Disoproxil Fumarate Among Cisgender Women. JAMA. 2024;331(11):930-937.

While emphasizing that although daily adherence is optimal, a minimum of 4 doses per week of F/TDF is expected to provide effective protection for most females

- Marrazzo, J., Tao, L., Becker, M., Leech, A. A., Taylor, A. W., Ussery, F., ... & Celum, C. (2024). HIV preexposure prophylaxis with emtricitabine and tenofovir disoproxil fumarate among cisgender women. Jama, 331(11), 930-937.

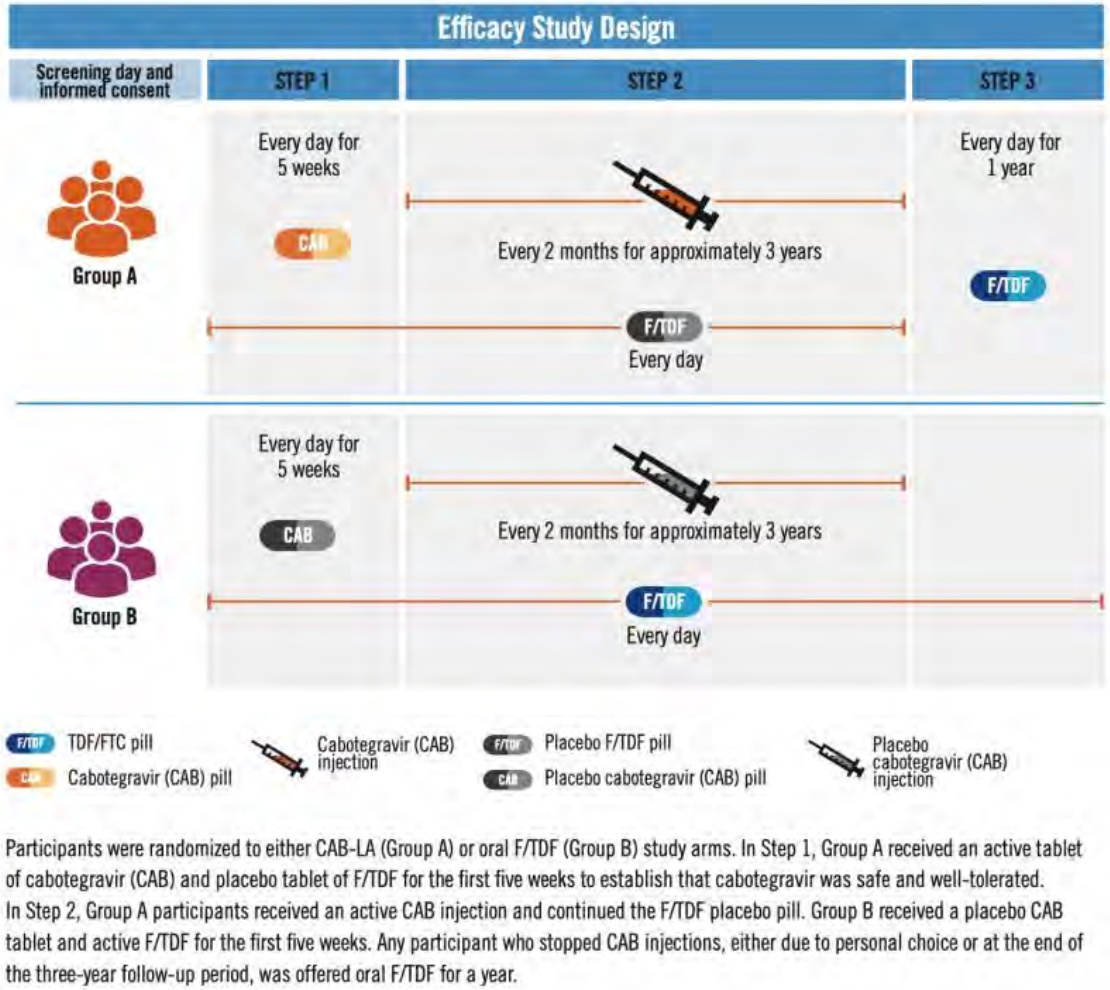
PrEP On-Demand For Women?



- Dumond JB et al (presenter Cottrell ML). Optimizing on-demand tenofovir disoproxil fumarate/emtricitabine dosing in women for HIV prevention. Conference on Retroviruses and Opportunistic Infections, San Francisco, abstract 157, 2025.

Long Acting Injectable Cabotegravir or “Apretude”

Long Acting Injectable Cabotegravir or “Apretude”



Participants were randomized to either CAB-LA (Group A) or oral F/TDF (Group B) study arms. In Step 1, Group A received an active tablet of cabotegravir (CAB) and placebo tablet of F/TDF for the first five weeks to establish that cabotegravir was safe and well-tolerated. In Step 2, Group A participants received an active CAB injection and continued the F/TDF placebo pill. Group B received a placebo CAB tablet and active F/TDF for the first five weeks. Any participant who stopped CAB injections, either due to personal choice or at the end of the three-year follow-up period, was offered oral F/TDF for a year.

- Results from two large-scale efficacy trials (HPTN 083 and HPTN 084) found that *injectable cabotegravir (CAB-LA), given every two months, was as effective as an oral form of pre-exposure prophylaxis (PrEP) in preventing HIV in:*
  - *Men who have sex with men*
  - *Transgender women who have sex with men*
  - *Cisgender women who have sex with men*
- FDA approved “Apretude” in December 2021

- https://www.avac.org/primer-long-acting-injectable-prep

Long Acting Injectable Cabotegravir or “Apretude”

Table 1. Recommended Dosing Schedule (with Oral Lead-in) for Pre-exposure Prophylaxis in Adults and Adolescents Weighing at Least 35 kg

Oral Lead-in (at Least 28 Days)	Intramuscular (Gluteal) Initiation Injection (Month 2 and Month 3)	Intramuscular (Gluteal) Continuation Injection (Month 5 and Every 2 Months Onwards)
Oral cabotegravir 30 mg by mouth once daily for 28 days	APRETUDE[a] 600 mg (3 mL)	APRETUDE[b] 600 mg (3 mL)

[a] Should be administered on the last day of oral lead-in or within 3 days thereafter.

[b] Individuals may be given APRETUDE up to 7 days before or after the date the individual is scheduled to receive the injections.

Table 2. Recommended Dosing Schedule (Direct to Injection) for Pre-exposure Prophylaxis in Adults and Adolescents Weighing at Least 35 kg

Intramuscular (Gluteal) Initiation Injection (Month 1 and Month 2)	Intramuscular (Gluteal) Continuation Injection (Month 4 and Every 2 Months Onwards)
APRETUDE[a] 600 mg (3 mL)	APRETUDE[a] 600 mg (3 mL)

[a] Individuals may be given APRETUDE up to 7 days before or after the date the individual is scheduled to receive the injections.

Cabotegravir Counseling

- Educational points to be covered with patients ***prior to*** **"ordering" and administering the medication**
  - ❑ Dosing schedule and the importance of the dose "window period"

Table 2. Recommended Dosing Schedule (Direct to Injection) for Pre-exposure Prophylaxis in Adults and Adolescents Weighing at Least 35 kg

Intramuscular (Gluteal) Initiation Injection (Month 1 and Month 2)	Intramuscular (Gluteal) Continuation Injection (Month 4 and Every 2 Months Onwards)
APRETUDE[a] 600 mg (3 mL)	APRETUDE[a] 600 mg (3 mL)

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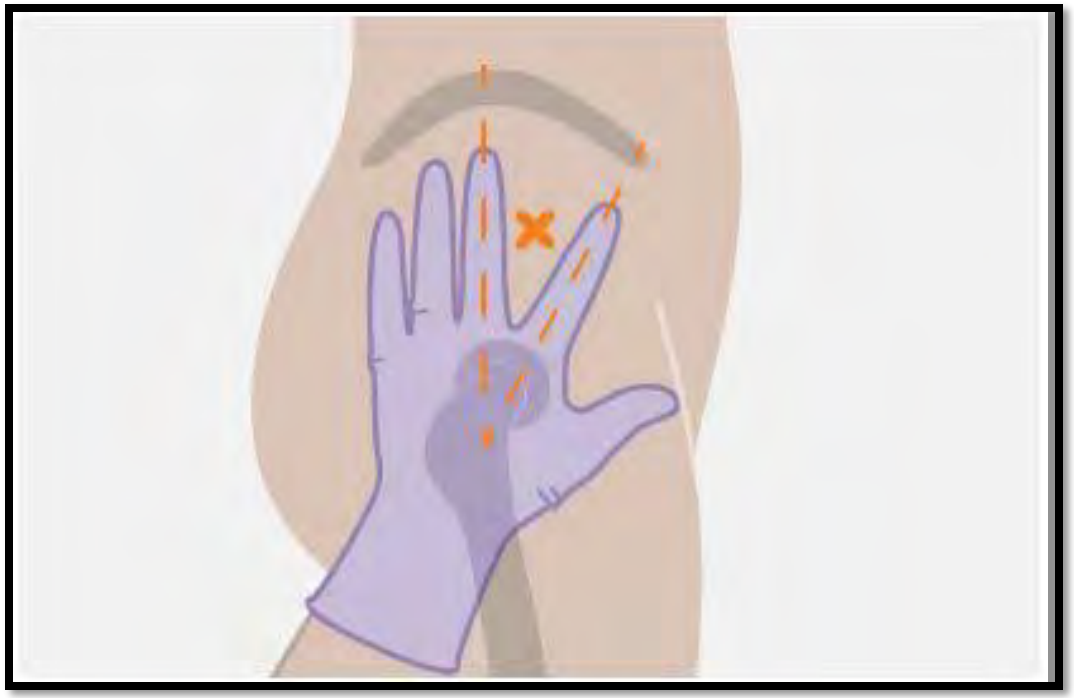
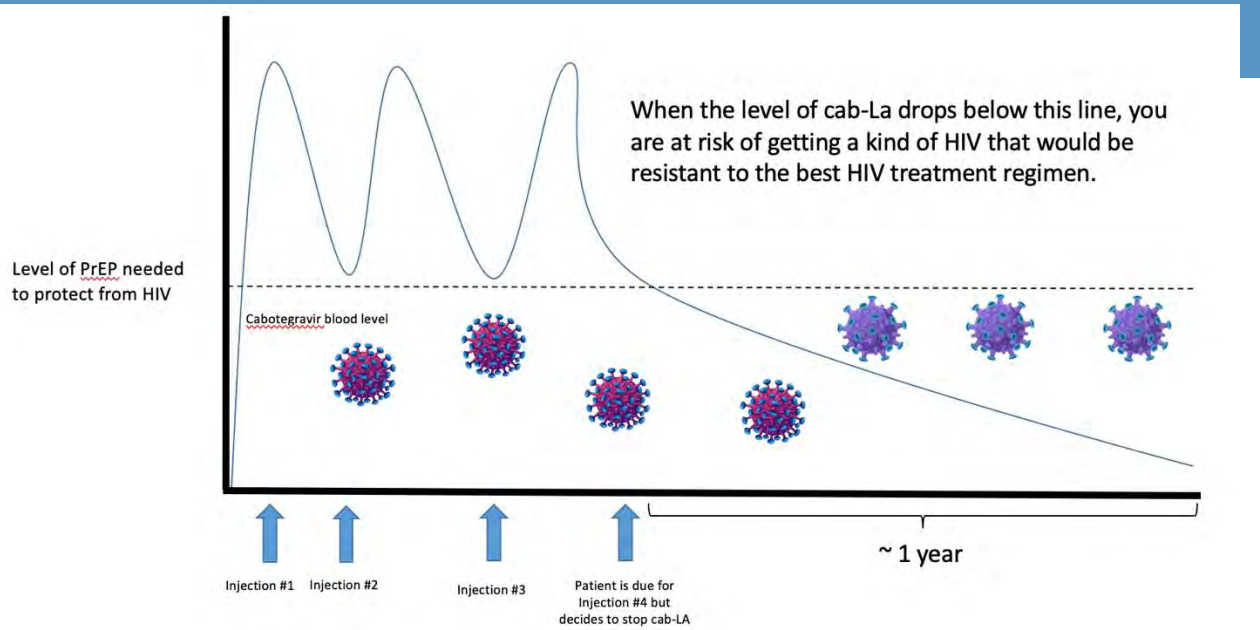
Cabotegravir Counseling

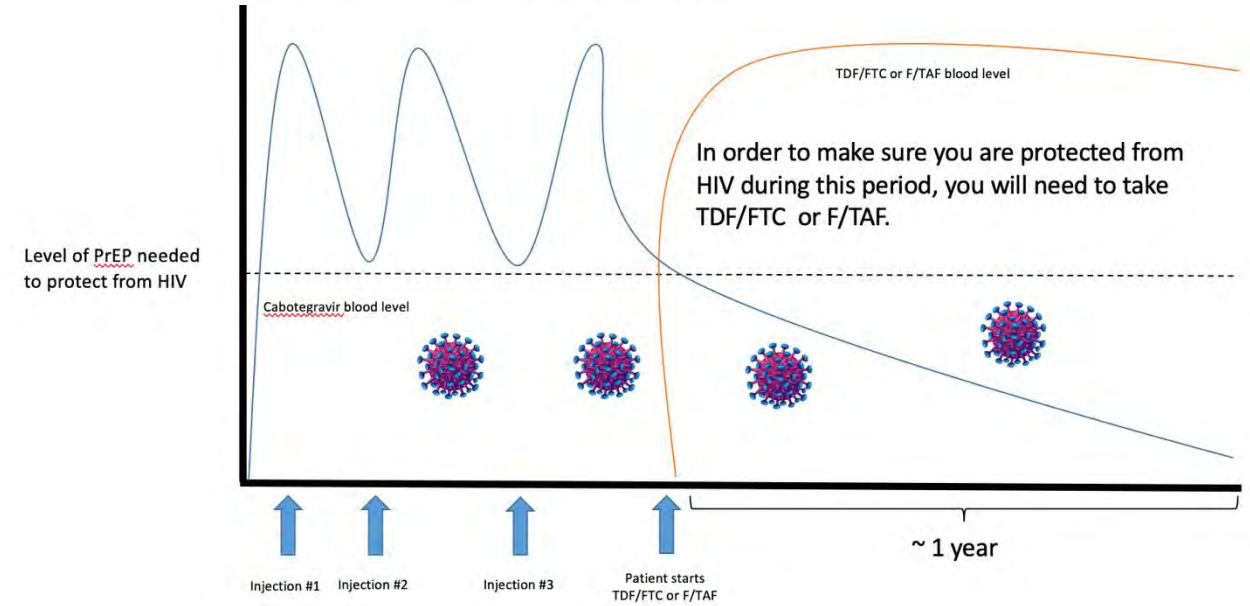
- Educational points to be covered with patients ***prior to*** **"ordering" and administering the medication**
  - ❑ Dosing schedule and the importance of the dose "window period"
  - ❑ Site of injection is gluteal



Cabotegravir Counseling

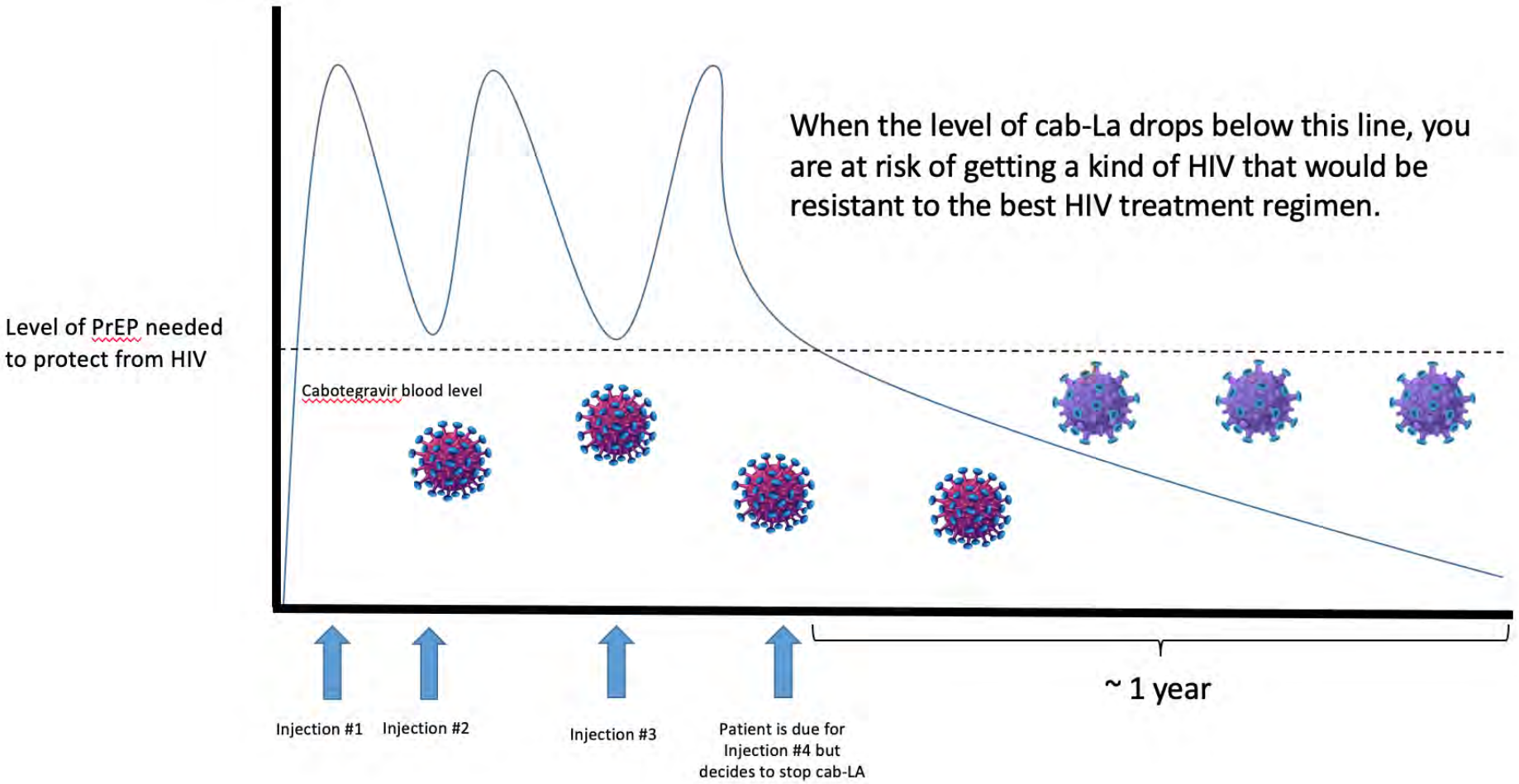
- Educational points to be covered with patients ***prior to*** **"ordering" and administering the medication**
  - ❑ Dosing schedule and the importance of the dose "window period"
  - ❑ Site of injection is gluteal
  - ❑ "Medication Tail"



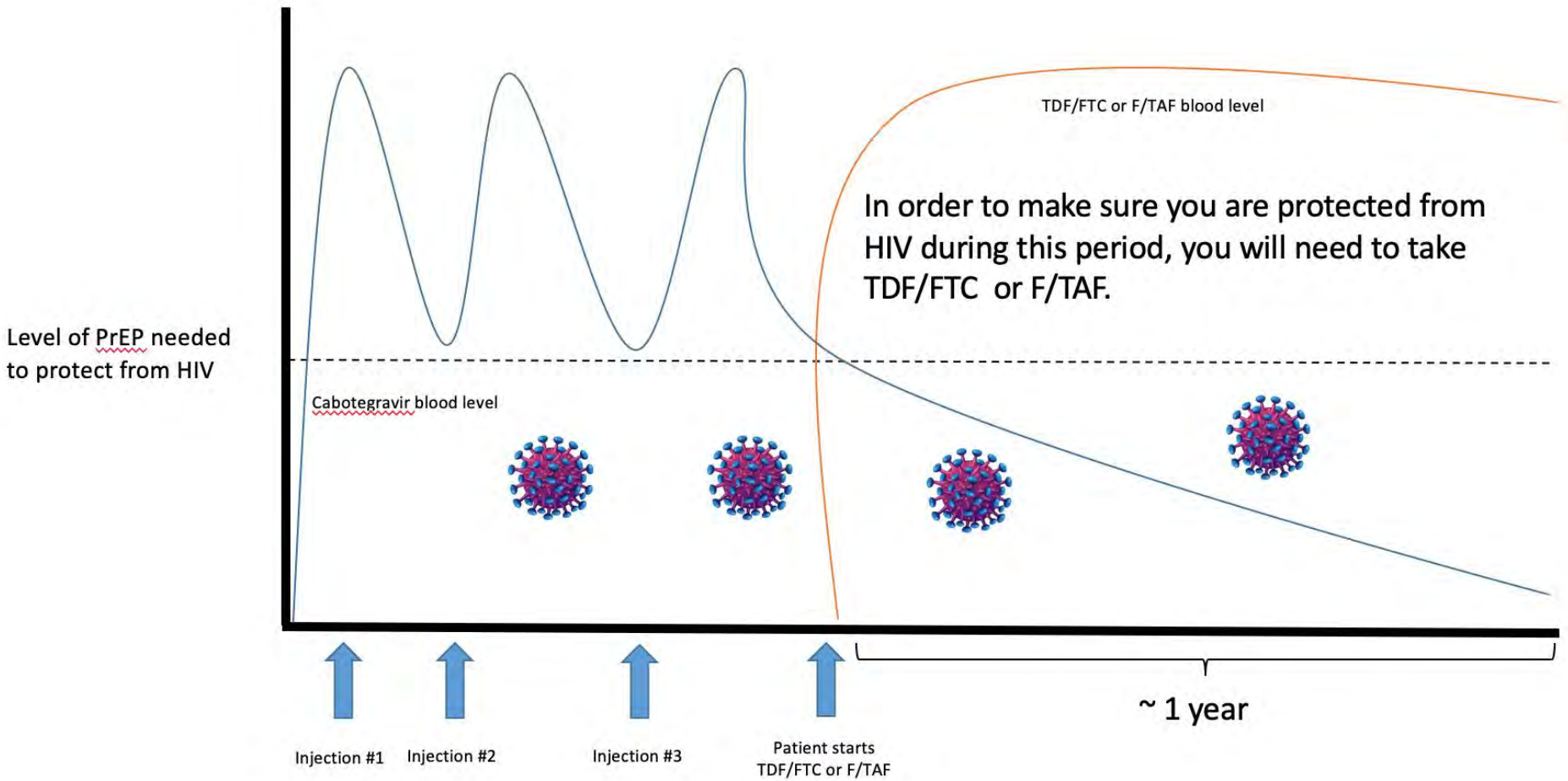


NEW YORK CITY STI HIV PREVENTION TRAINING CENTER

Medication Tail Infographics



Medication Tail Infographics



Cabotegravir Counseling

- Educational points to be covered with patients ***prior to*** **"ordering" and administering the medication**
  - ❑ Dosing schedule and the importance of the dose "window period"
  - ❑ Site of injection is gluteal
  - ❑ "Medication Tail"
  - ❑ Medication side effects
    - ❑ Plan for depressive symptoms

5.6 Depressive Disorders

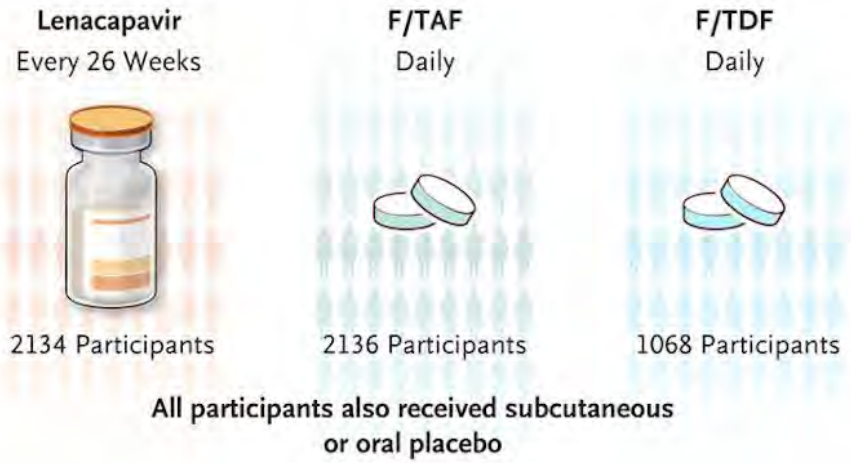
Depressive disorders (including depression, depressed mood, major depression, persistent depressive disorder, suicide ideation or attempt) have been reported with APRETUDE *[see Adverse Reactions (6.1)]*. Promptly evaluate individuals with depressive symptoms to assess whether the symptoms are related to APRETUDE and to determine whether the risks of continued therapy outweigh the benefits.

Coming soon… Lenacapavir for Prevention

- FDA Approval is slated for June 2025
- Len is a capsid inhibitor
- It is delivered via **two subcutaneous injections** to the abdomen **every six months**
- Lenacapavir has been used since 2022 as part of a regimen for HIV positive patients with a multi-drug resistant virus
- The Purpose Trials have demonstrated to reduce HIV infections by 100%

HOW WAS THE TRIAL CONDUCTED?

Adolescent girls and women who were HIV-negative at baseline were assigned to receive subcutaneous lenacapavir every 26 weeks, daily oral F/TAF, or daily oral emtricitabine–tenofovir disoproxil fumarate (F/TDF; active control) for 104 weeks. All participants also received the alternate subcutaneous or oral placebo. The primary objective was to determine the efficacy of lenacapavir and F/TAF by comparing the incidence of HIV infection among participants with the estimated background incidence in a cross-sectional screened incidence cohort.



The NEW ENGLAND JOURNAL of MEDICINE

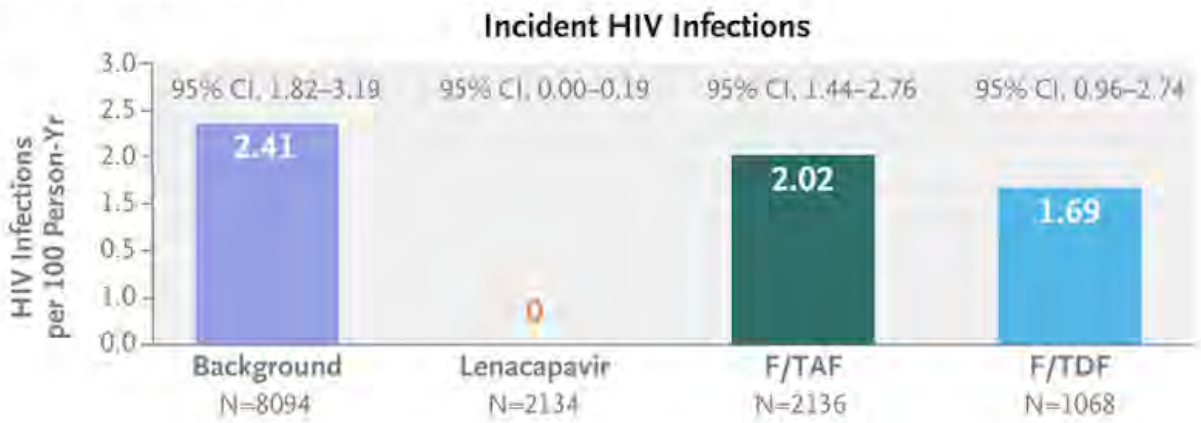
Twice-Yearly Lenacapavir for HIV Prevention

A PLAIN LANGUAGE SUMMARY

RESULTS

Twice-yearly lenacapavir reduced HIV incidence by 100% as compared with background HIV incidence and by 100% as compared with daily oral F/TDF. No adolescent girls or young women who received lenacapavir acquired HIV infection.

HIV incidence with F/TAF did not differ significantly from background HIV incidence, and there was no meaningful difference in HIV incidence between F/TAF and F/TDF.



CONCLUSIONS

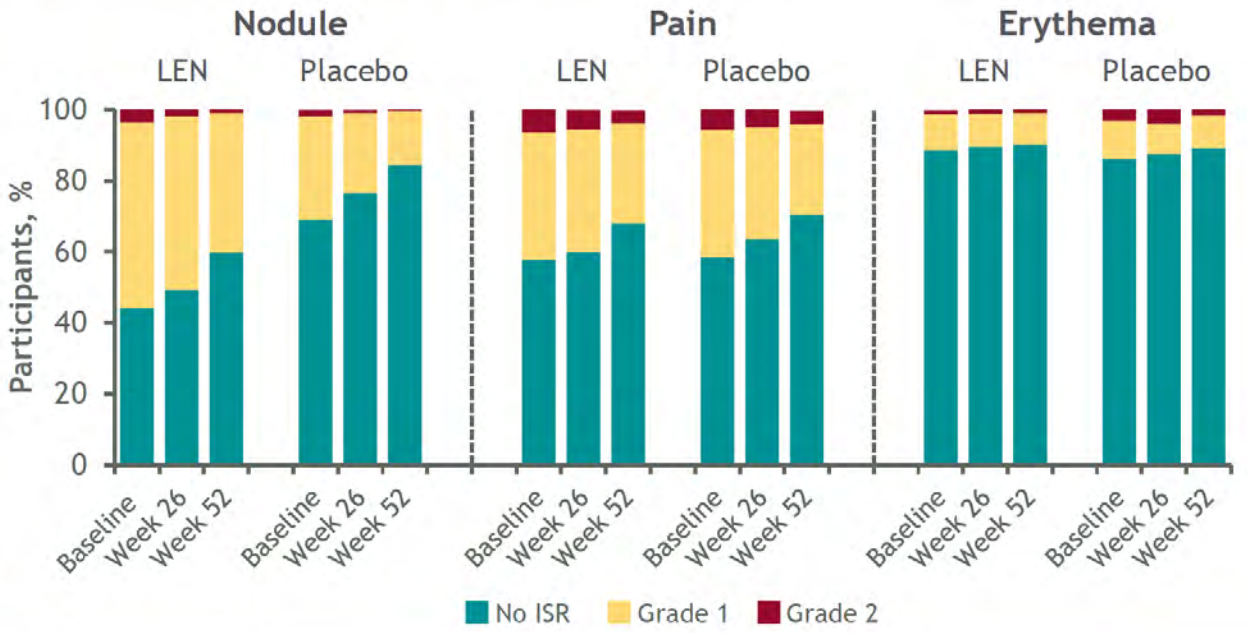
In a randomized, controlled trial involving cisgender adolescent girls and young women in South Africa and Uganda, twice-yearly subcutaneous lenacapavir was superior to daily oral emtricitabine–tenofovir disoproxil fumarate in preventing HIV infection.

- https://www.nejm.org/doi/full/10.1056/NEJMoa2407001

Lenacapavir for PrEP

Injection-Site Reaction Frequency and Grade Diminish With Subsequent Injections

- LEN is injected into the SC space and forms a drug depot that may be palpable under the skin but is usually not visible
- As the drug elutes over time, the depot gets smaller, and the nodules resolve or reduce in size substantially prior to the next injection
- **The frequency of ISRs, including nodules, decreased with subsequent doses (also observed previously in PURPOSE 1[1] and with HIV treatment[2])**



Among 15,239 LEN or placebo injections, only 29 participants discontinued due to AEs of ISRs; 26 in LEN group and 3 in the F/TDF group

1. Bekker L-G, et al. N Engl J Med. 2024;391:1179-92. 2. Kumar P, et al. Abstract EPB184 presented at the 24th International AIDS Conference, July 29 to August 2, 2022; Montreal, Canada.

NYC STI Prevention Training Center (PTC)

The CDC-funded NYC STD Prevention Training Center at Columbia University provides a continuum of education, resources, consultation and technical assistance to health care providers, and clinical sites. *Region: Ohio, Indiana, Michigan, New York, New Jersey, Puerto Rico & the US Virgin Islands*

https://www.publichealth.columbia.edu/nycptc

Didactic Presentations

Webinars, conferences, trainings and grand rounds presentations to enhance and build knowledge

Technical Assistance

Virtual and on-site technical assistance regarding quality improvement, clinic implementation and best practices around sexual health provision

For more information please contact:
nycptc@cumc.columbia.edu

Clinical Consultation Warmline

Clinical guidance regarding STD cases; no identifying patient data is submitted
www.stdccn.org

Resources

Clinical guidance tools regarding the STD treatment guidelines, screening algorithms and knowledge books, such as the **Syphilis Monograph**.

To download a copy please visit:

https://www.publichealth.columbia.edu/file/15568/download?token=exDNYpJ-